UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

CORRECTED ROXANE LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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I. INFORMATION AVAILABLE TO THE GOVERNMENT REGARDING THE DIFFERENCE BETWEEN AWP AND ACTUAL ACQUISITION COSTS: 1980 – 1989

1. In 1984, the Office of Inspector General ("OIG") reported that pharmacies could purchase drugs at widespread discounts off of AWP, including as much as 41.8% below AWP (which translates to a 72% spread under Plaintiffs' methodology for calculating spread). (Tab 71, Helms Ex. 5, OIG July 1984, *Changes to the Medicaid Prescription Drug Program Could Save Millions*, at 4, 10 (July 1984 OIG Report).) The OIG's recommendations to HCFA included the following: (1) that HCFA revise its policy and regulations to provide more oversight over Medicaid drug reimbursement, including insertion of "language that will preclude the general use of AWP as the State agencies' 'best estimate of prices providers generally are paying for drugs'"; and (2) that HCFA "[w]ork with State agencies in developing alternative drug reimbursement methodologies which more closely approximate the prices pharmacies pay for drugs." (*Id.* at 23.) The OIG's report was based on its ongoing review of prices at which the nations' wholesalers resold drugs to pharmacies. (*Id.* at 2, 11.) In its report, the OIG stated and concluded the following:

- Because of AWP reimbursement, "[e]xcessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program." (*Id.* at 3.)
- "The use of AWP in determining Medicaid reimbursement for drugs has been a problem that HCFA has recognized for some time." (*Id.*)
- "HCFA believed that published AWP was too high and, therefore, the purpose of the EAC requirement in the regulations was to move states away from using AWP as the upper limit for reimbursing drug ingredient cost. (*Id.* at 3, 22.)
- "Our review . . . showed that pharmacies rarely purchased the sample drugs at the published AWP. . . . Most of the purchases – 3,455 (99.6 percent) – were made at prices averaging about 16 percent below AWP. These drug purchases ranged from as little as .23 percent below AWP to as much as 42 percent below AWP." (*Id.* at 4.)

- "Our examination of 1,127 direct purchase invoices showed that prices to pharmacies averaged 21.2 percent below AWP; ranging from as little as 6.3 percent below AWP to as much as 41.8 below AWP." (*Id.* at 10.)

- "The use of AWP as an upper limit for Medicaid drug reimbursements is a nationwide problem which is resulting in significant unnecessary program expenditures." (*Id.* at 15.)

- On average, pharmacies purchased drugs for 15.96 percent below AWP. (*Id.* at 15.)

- "[W]e believe that as much as $128 million ($72 million Federal share) in Medicaid expenditures could be saved annually if program policy and regulations were revised so as to require States to abandon the AWP reimbursement methodology in favor of drug pricing systems which would more closely estimate the prices pharmacies generally pay for drugs." (*Id.* at 16.)

- "[P]harmacies do not purchase drugs at the AWP published in the 'Bluebook,' 'Redbook,' or similar publications. Thus, AWP cannot be the best—or even an adequate—estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices." (*Id.* at 22.)

- "The revised regulations should eliminate the use of AWP and require State Medicaid agencies to aggressively pursue alternative methods for establishing upper reimbursement limits." (*Id.*)

- "[O]ur report demonstrates on a nationwide basis that pharmacies are purchasing drugs at prices considerably below published AWP. Thus, AWP is not an adequate estimate of the prices providers generally are paying for drugs." (*Id.* at 24.)

- "[O]ur report demonstrates that the Medicaid program is currently reimbursing pharmacies amounts for drug ingredient cost that are significantly in excess of the pharmacies' actual costs of the drug ingredients—which is contrary to the intent of the existing Federal regulations." (*Id.* at 25.)

2. In 1987, the Committee on Ways and Means, Subcommittee on Health, House of Representatives—the committee with budgetary oversight over the Medicare and Medicaid programs—heard testimony from the GAO on "Issues Related to Possible Coverage of Outpatient Prescription Drugs Under Medicare." (Tab 72, June 2, 1987, Testimony of Michael Zimmerman, *Issues Related to Possible Coverage of Outpatient Prescription Drugs Under*

Medicare, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/T-HRD-87-15.) In that hearing, Michael Zimmerman, Senior Associate Director, Human Resources Division, testified as follows:

- The AWPs contained in Red Book and Blue Book "do not reflect many types of discounts and rebates available to pharmacies and, thus, tend to overstate pharmacies' drug costs." (*Id.* at 3.)

- "In the mid-1970's, the Department of Health and Human Services (HHS) estimated that AWPs overstated actual costs by 15 to 18 percent." (*Id.*)

- "In the final analysis, the question of how much to pay for a drug comes down to the degree of assurance desired that the pharmacy is not overcompensated and that the program does not pay for expensive brand name drugs when therapeutically equivalent generics are available. The better the estimate of what the pharmacy pays for a drug, the more assurance the pharmacy is not overpaid. And the more incentives to dispense lower cost drugs, or only paying the price of lower cost drugs, the more assurance that high priced drugs are not paid for when equivalent, lower cost ones are available." (*Id.* at 4.)

3. On July 5, 1987, the Kentucky-based *Lexington Herald-Leader* published a front-page story entitled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." (Tab 73, Lockwood Ery 15 at 1, July 5, 1987, John Winn Miller, "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars, *Lexington Herald-Leader*, at A1.) The article included the following-information:

- A pharmaceutical representative and a Pennsylvania Medicaid official told the *Herald-Leader* that "(Average Wholesale Price) is a joke," and AWP "just doesn't mean anything. It has no connection to what pharmacists really purchase the drug for." (*Id.* at 3.)

- "Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor, according to government and industry officials." (*Id.* at 1.)

- Manufacturers use a "sales technique called 'playing the spread.'" A large "spread, or difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit." (*Id.* at 4-5.)

- Some "companies actually advertised that they had a better spread" and "many companies routinely list Average Wholesale Prices and 'your price' in their catalogs to show the spread." (*Id.* at 5.)

- Kentucky Medicaid officials discovered that one drug was listed "in the 1987 Red Book as having an Average Wholesale Price of 16.69 cents for each 260 mg. tablet," but the drug "was being sold to pharmacies for only 8.88 cents a tablet – 47 percent below the published Average Wholesale Price." (*Id.* at 4.) Under Plaintiffs' methodology, this is an 88% spread.

- The Government was aware of the issue, but previous attempts to change the system had "met bitter resistance" from pharmacists and other groups, which had forced HCFA to back down from making changes. (*Id.* at 8-9.)

- The National Association of Retail Druggists "led the fight to force the federal Health Care Financing Administration . . . to retreat from proposed changes in 1985 that came up after the inspector general's audit discovered the overpayments." (*Id.*)

- According to the Vice President for Communications of the National Association of Retail Druggists, the Association "'put a lot of pressure on the Health Care Financing Administration, and they backed off." (*Id.* at 3, 9.)

4. In February 1989, the *Philadelphia Inquirer* published an article entitled "When Drugstores Tell You No." (Tab 74, Feb. 12, 1989, Barbara Demick, "When Drugstores Tell You No," *Phila. Inquirer* at G01.) The article included the following information:

- "In a recent study . . . it was found that drugstores actually pay 15 percent less than average wholesale price for brand-name prescription drugs and up to 50 percent less for generics." (*Id.*) Under Plaintiffs' methodology, this is a 100% spread.

5. In February 1989, *Newsday* published an article entitled "No Rx for Plans; Drug Plans Draw Pharmacists' Ire." (Tab 75, Feb. 24, 1989, Elizabeth Sanger, "No Rx for Plans; Drug Plans Draw Pharmacists' Ire," *Newsday* (New York), at 47.) The article included the following information:

- "While drug stores maintain they can't make money on a discounted average wholesale price, insurers say the average wholesale price isn't the price they pay for drugs. Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price." (*Id.*)

6. In March 1989, the *Arkansas Democrat-Gazette* published an article entitled "Pharmacists Face Big Losses Under Proposal, Official Says." (Tab 76, Mar. 23, 1989, "Pharmacists Face Big Losses Under Proposal, Official Says," *Arkansas Democrat-Gazette*.) The article included the following information:

- HCFA "recently ruled that the average wholesale price [was] no longer an acceptable reimbursement standard." (*Id.* at 1.)

- "Bill McCutcheon of Dallas, deputy regional administrator of the Health Care Finance Administration, said numerous studies and 'open admission by the people who publish those prices' has shown that the average wholesale price 'doesn't represent the actual cost' to pharmacies 'by any stretch of the imagination.' Druggists actually pay less, he said." (*Id.*)

7. In April 1989, the *Washington Post* published an article entitled "Prescription Drug Plans Face Threat; Pharmacy Chains Dropping Programs." (Tab 77, April 14, 1989, Lena H. Sun, "Prescription Drug Plans Face Threat; Pharmacy Chains Dropping Programs," *The Washington Post*, at A1.) The article included the following information:

- "The generally accepted practice in the industry has been to use 'the average whole price'—something akin to the 'blue book' value of an automobile—as a way to measure the cost of the drug." (*Id.* at 2.)

- "A study commissioned by Mack Trucks . . . found that drugstores purchased many individual brand-name prescription drugs for 15 percent less than the average wholesale price, and paid as much as 50 percent less for generic drugs." (*Id.*) Under Plaintiffs' methodology, this is a 100% spread.

8. In May 1989, *Drug Store News* published an article entitled "AWPs Are a Joke, But No One Is Laughing." (Tab 78, May 1, 1989, Harold Cohen, *AWPs Are a Joke, But No One Is Laughing*, Drug Store News.) The article included the following information:

- "In many instances, AWP actually stands for the highest price at which manufacturers sell their product. If, in fact, a true AWP was assigned to a product, taking into consideration all the various pricing schedules available from drug manufacturers, the AWP would be a much lower number than is normally used." (*Id.*)

- "AWP is being manipulated by many pharmaceutical manufacturers, both generic and branded, to get their products on state, federal and third-party formularies. The

feeling is 'Give the pharmacists a higher AWP and they will use or substitute the product with the best AWP to receive a higher rate of reimbursement.'" (*Id.*)

- "Let's face it . . . AWP is a joke, and the folks who run third-party programs are finally recognizing it for what it is, an easy target. I cannot support efforts afoot by segments of the retail pharmacy industry to keep profits made off of phony AWPs by calling them 'earned discounts.'" (*Id.*)

- "[T]he AWP issue may become a moot point once retail pharmacy feels the full impact of the Medicare Catastrophic Drug Act in 1991. According to the law, the AWP is to be determined by the Secretary of Health and Human Services. Once the AWP is in government's hands it will never be the same. It will be scrutinized and uncovered for what it is—a sham. Today's AWP doesn't stand for 'Average Wholesale Price' anymore; it really means 'Against the Working Pharmacist.'" (*Id.*)

9. In July 1989, the United States Senate held a hearing entitled "Skyrocketing Prescription Drug Prices: Are We Getting Our Money's Worth?" (Tab 79, Abbott Ex. 154, July 18, 1989, *Skyrocketing Prescription Drug Prices: Are We Getting Our Money's Worth?: Hearing Before the S. Comm. on Aging*, 101st Cong. (1989).) The hearing included the following testimony:

- Louis B. Hays, Acting HCFA Administrator in charge of Medicaid, testified that "[w]hile the term 'average wholesale price' is suggestive of the amount that pharmacies actually pay for drugs, it is in fact, significantly higher than actual costs. The average wholesale price is somewhat comparable to the manufacturer's sticker price on a new car." (*Id.* at 210, 214 (statement of Louis B. Hays, Acting HCFA Administrator in charge of Medicaid).) "[T]his is rarely the price actually paid for the car." (*Id.* at 214-15.)

- Administrator Hays further testified that "there have been a number of studies which indicate that published average wholesale price for drugs overstates the actual prices paid by as much as 10 to 20 percent, because of discounts, special offers, or purchasing incentives." (*Id.* at 210.)

- Administrator Hays also noted that "[u]nder current law, HCFA has no authority to negotiate more competitive prices or demand the discounts warranted by the large volume of business the Medicare program represents. Indeed, the statute requires us to exclude from the price survey the discounts which pharmacies typically receive from drug companies. Thus, the survey prices will overstate actual pharmacy costs. Multiple source drugs make up the lion's share of the prescription drug market, and, essentially, Medicare will pay the average wholesale price for these drugs." (*Id.* at 214.)

- Veterans Affairs Department Pharmaceutical Products Division Chief Dennis Sytrsky testified that "For multiple-source products . . . the department 'typically' obtains 'discounts ranging from 39% to 93%, but most multiple-source drugs in our depots are currently being purchased with discounts of greater than 80%' off AWP." (Tab 80, Abbott Hayashi Ex. 8 at 1, July 24, 1989, "V-A Obtains Rx Drug Price Discounts of 41% for Single Source, 67% for Multisource Drugs not Distributed by Department, Pryor Drug Price Hearing Told," *The Pink Sheet*.) These translate into spreads (under Plaintiffs' methodology) of 64%, 1,328%, and 400%, respectively.

- Senator David Pryor, the Committee Chairman, informed the committee that a bottle of Motrin 800 mg "is priced at $29 to the public—including Medicare—but only $8 to hospitals and $5 to V-A. The published price (AWP) . . . is $32." (*Id.*)

10. Following the hearing, in August 1989, the Senate Committee on Aging authored a report entitled *Prescription Drug Prices: Are We Getting Our Money's Worth?*, Majority Staff Report of the Special Committee on Aging, S. Rep. 101-49, 191st Cong., Aug. 1989 (Tab 81, Aug. 1989 Senate Report).) The report stated and concluded the following:

- Hospitals, HMOs and nursing homes achieved discounts up to 99% off of AWP, which is the equivalent of a 9,900% spread using Plaintiffs' methodology. (*Id*. at 11; *see also* Tab 80, Abbott Hayashi Ex. 8 at 2-3.)

- "There are two markets in the United States for most big-selling prescription drugs: a price-competitive market characterized by deep discounts off the published list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs." (Aug. 1989 Senate Rep. at 10.)

- The Department of Veterans Affairs received on average a 67% discount off of published AWP for generic drugs, as well as 41% off published AWP for single-source drugs. (*Id*. at 11.)

11. In September 1989, the OIG reported to HCFA that drugs could be purchased at significant discounts off of AWP, including an average of 18.2% off AWP for generic drugs, (Tab 82, Dey Ex. 46 at 4-5, OIG Sept. 1989, "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program, A-06-89-00037, (1989 OIG Report)), which is a 22% spread under Plaintiffs' methodology. The OIG specifically recommended that: (1) the use of AWPs by HCFA in the Medicaid or Medicare programs "should be discontinued" (*id.* at 7); (2) if HCFA decided to continue using

AWP for Medicare, AWP should be discounted (*id.*); and (3) in the Medicaid program, HCFA "require State agencies to discount AWP when making program reimbursements." (*Id.*) The report was a continuation of the OIG's 1984 study, which reviewed prices at which the nation's largest wholesalers resold drugs to pharmacies. (*Id.* at 4.) The OIG report also included the following statements and conclusions:

- "[T]he preponderance of the evidence shows that AWP is heavily discounted" and that "AWP overstates the prices as much as 10 to 20 percent." (*Id.* at 1.)
- Between 1984 and 1989, the OIG noted a "much wider base of awareness" of the variances between AWPs and acquisition costs. (*Id.*) All "facets of the industry are willing to admit that . . . discounts [from AWP] exist." (*Id.* at 6.)
- "We continue to believe that AWP is not a meaningful figure, and that it should not be used for making reimbursements in either the Medicaid or the new Medicare drug program." (*Id.* at 1.)
- HCFA should abandon use of AWP for both the Medicaid and Medicare drug programs. (*Id.* at 1, 2, 7.)
- "Concerning Medicare, we are recommending that HCFA study the feasibility of other reimbursement methods that do not involve AWP and seek legislative changes to permit either the use of a different method or the discounting of AWP." (*Id.* at 2.)
- On average, pharmacies bought drugs for 15.5 percent below AWP. (*Id.* at 1, 4.) For single-source drugs, the average discount off AWP was 14.39 percent. (*Id.* at 4.) Multi-source drugs had a weighted average price below AWP of 18.2 percent. (*Id.*)
- "[W]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare programs. When AWP is used, we believe that it should be discounted." (*Id.* at 7.)
- Several wholesalers made the following representations to OIG:
  - "AWP is a meaningless figure." (*Id.* at 5.)
  - "[I]t is recognized in the industry that there are discounts off AWP . . . selling price is based on AWP less a discount or . . . cost plus a markup." (*Id.*)
- OIG also noted quotes from the 1989 *Lexington Herald-Leader* article:
  - "The (Average Wholesale Price) is a joke . . . it has largely become a farce because many companies have abused it and continue to abuse it." (*Id.* at 6.)

- AWP "just doesn't mean anything. It has no connection to what pharmacies really purchase the drug for." (*Id.*)

II. GOVERNMENT POLICY DECISIONS TO MAINTAIN AWP AND NOT USE ACTUAL ACQUISITION COST AS THE BASIS FOR REIMBURSEMENT: 1980 – 1991

12. In July 1987, HCFA established the FUL program for multisource drugs. (*See* Tab 83, Abbott Ex. 284, Medicare and Medicaid Programs; Limits on Payments for Drugs, 52 Fed. Reg. 28648 (July 31, 1987).) Rather than adopting a formula based on actual acquisition costs, HCFA capped reimbursement at 150 percent of the lowest published price. HCFA also encouraged states to allow pharmacies to retain profits on generic drug purchases:

- HCFA encouraged "State agencies [to] be innovative in these programs and find ways to assure the availability at reasonable prices of multiple-source drugs. One way they could do this would be to encourage retail pharmacy participation in the Medicaid program by permitting them to retain profits from the sale of listed drugs to Medicaid recipients." (*Id.* at 28653.)

- "In the previous section, we discussed the possible effects of building into our rates for ingredients a profit margin for pharmacists. We expressed the hope that States would recognize the advantage of providing pharmacists with an incentive to participate in the Medicaid program and to stimulate pharmacists to engage in prudent purchasing practices and the substitution of lower cost therapeutically equivalent products." (*Id.* at 28656.)

- HCFA's choice of a 150 percent markup was made "in order to meet the following two objectives: (1) That the markup be high enough to assure that pharmacists can normally obtain and stock an equivalent product without losing money on acquisition costs of incurring the expense of departure from normal purchasing channels, and (2) that the markup not be so high as to cost the Medicaid program unnecessary money." (*Id.* at 28653.)

13. Based primarily on the July 1984 OIG Report, in August 1989, HCFA issued a revision to the State Medicaid Manual, which acknowledged the following as to brand name drugs and drugs other than multiple source drugs:

- "[T]here is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc. Consequently, absent valid documentation to the contrary, a

published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers." (Tab 84, Marmor Ex. 16, HCFA Payment for Services § 6305.1.B, 1989 Revisions at 6-72; 1989 OIG Report at 1-2.)

14. In 1989, HCFA sent a Transmittal Notice to State Medicaid agencies alerting them that "nondiscounted or unmodified AWP is not acceptable for State use as the basis for estimated acquisition cost (EAC), absent any compelling evidence to the contrary." (Tab 85, Roxane Ex. 121, Jan. 31, 1989 HCFA Transmittal Notice, Region IV, "Use of Nondiscounted Average Wholesale Price (AWP) as Estimated Acquisition Cost (EAC) in Medicaid Drug Reimbursement.") It added that "HCFA's policy is that there is a preponderance of evidence that indicates that AWP significantly overstates the prices that pharmacists are currently paying for drug products." (*Id.*) HCFA informed the states that if they were using an undiscounted or unmodified AWP, they would be required to "justify their use of AWP with appropriate data." (*Id.*)

15. Citing the findings of the 1984 and 1989 OIG studies, in June 1991, HCFA proposed a reimbursement formula of AWP-15% for Medicare Part B drugs. (Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 25792, 25800, 25860 (June 4, 1991) (proposed rule)). HCFA stated that "based on studies by the Office of the Inspector General . . . and other information, we believe that the Red Book and other wholesale price guides substantially overstate the true cost of drugs." (*Id.* at 25800)

16. Because of provider and access concerns, however, HCFA rejected this proposal and instead, in November 1991, HCFA adopted a rule that reimbursement for Medicare Part B drugs be at the lower of 100% AWP or EAC. (Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 59502, 59525 (Nov. 25, 1991 (final rule) (codified at 42 C.F.R.

§§ 405.517, 415.36)). Comments received by HCFA in response to the proposed regulations, and HCFA's response thereto, included the following:

- "We received a great many comments on this issue, primarily from oncologists indicating that our 85 percent standard was inappropriate. The thrust of most of the comments was that many drugs could be purchased for considerably less than 85 percent of AWP—particularly multi-source drugs—while others were not discounted. Other commenters suggested that, while pharmacies and perhaps large practices could receive substantial discounts on their drug purchases, individual physicians could not. The bulk of the comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs." (*Id.* at 59524.)

- "Response: After considering all of the comments on this issue, we have decided to modify the proposed policy. Payment for drugs would be based on the lower of the national AWP or the Medicare carrier's estimate of actual acquisition costs. Since there can be many wholesale prices listed for each drug because of multiple sources for the drug, we are defining the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians, or other providers as appropriate, actually pay for the drugs." (*Id.* at 59525.)

III. ADDITIONAL INFORMATION ESTABLISHING THE DIFFERENCE BETWEEN AWP AND ACTUAL ACQUISITION COSTS: 1990 – 1999

17. In June 1990, *Drug Store News* published an article entitled "There's Nothing 'Average' About AWP." (Tab 86, June 11, 1990, Harold Cohen, "There's Nothing 'Average' About AWP," *Drug Store News*.) The article included the following information:

- "AWP has become an exploited figure that is often picked out of thin air by pharmaceutical manufacturers who know that as long as third-party programs continue to use AWP as a base for reimbursement, the higher the number the better their chances are of getting their product dispensed. But there's nothing average about AWP. . . . The AWP of today is not the same AWP of 25 years ago." (*Id.*)

18. Thomas A. Scully, senior White House staff member on health care from 1990-91, and HCFA/CMS Administrator from May 2001 through January 2004 (Tab 46, 05-15-07 Scully Dep. 97, 50), understood that AWP was not an actual acquisition cost as early as 1991:

- Since 1990-91, Scully believed that AWP itself was "air"—a "completely contrived number," and that the reimbursement system was "insane." (*Id.* at 194-95, 133-34.)

- Since 1990-91, Scully was aware that hospitals were pocketing revenue and margins from the spread between AWP and acquisition costs. (*Id.* at 44-46.)

- Scully characterized the reimbursement policy, whereby hospitals would, for example, "acquire drugs for . . . 5 or 600 dollars" and get reimbursed by Medicare at "95 percent of average wholesale price, which was frequently 1500 dollars or more," as "insane" and "absurd." (*Id.*)

19. Between December 1991 and October 1992, the United States General Accounting Office (GAO) conducted a study of nine pharmacies in Illinois and Maryland "to determine the differences between what the pharmacies were reimbursed by Medicaid for outpatient drugs and what they paid." (Tab 87, Abbott Ex. 458 at 3-4, GAO March 18, 1993, *Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland* (1993 GAO Report).) In March 1993, the GAO published the results of its study, revealing that purchase prices for the pharmacies they studied "ranged from 16 to 42 percent less than AWP" (*id.* at 5-6.), which translates to 19 to 72 percent spreads under Plaintiffs' methodology for calculating spread. The study showed that on average, pharmacies "paid an average 26 percent less than AWP for the drugs" (which translates into a spread of 35 percent under Plaintiffs' methodology). (*Id.* at 5.) The report also noted that "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs. However, because the officials did not have current data on dispensing costs, they did not know what dispensing fees should be." (*Id.* at 6.)

20. In January 1994, the GAO conducted an additional study. In a report comparing prices for pharmaceuticals in the United States to prices in the United Kingdom, the GAO noted "Some observers have criticized the use of WAC as a measure of manufacturers' prices because it does not capture manufacturers' discounts and prices to certain customers. However, the WAC is the correct measure for an analysis of the undiscounted segment of the U.S. pharmaceutical market." (Tab 88, GAO Report to the Chairman, Subcommittee on Health and

the Environment, Committee on Energy and Commerce, House of Representatives, Prescription Drugs; Companies Typically Charge More In The United States than in the United Kingdom (Jan. 1994) at p. 19, n.16.)

21. In August 1994, the OIG began conducting a nationwide review of the difference between published AWPs and pharmacies' actual acquisition costs of generic drugs in the Medicaid program, by focusing on a random sample of eleven states. (Tab 7, 06-24-08 Chesser Dep. 66; Tab 89, Roxane Ex. WY 4, OIG Aug. 4, 1997, *Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-97-00011, Aug. 4, 1997 ("Aug. 1997 OIG Report").) Based on the results of the 1994-95 study, in 1997, the OIG informed HCFA that the nationwide average acquisition cost was 42.5% below AWP—a spread of 74%. (Tab 89, Aug. 1997 OIG Report at 4.) The study culminated in a series of state-specific reports published by the OIG and the August 1997 OIG Report. The OIG recommended that HCFA "work to ensure that states reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report." (*Id.* at Appendix 3, p. 2.) In its report, the OIG stated and concluded the following:

- Discounts off AWPs for generic drugs were on average 42.5%—the equivalent of a 74% spread under Plaintiffs' methodology. (*Id.* at 4.)
- "An article in the June 10, 1996 issue of *Barron's* entitled, 'Hooked on Drugs,' focused additional attention on AWP and its relationship to actual acquisition cost. *Barron's* compared about 300 dose forms of the top 20 Medicare drugs and concluded that the true cost was 10 to 20 percent below AWP for brand name drugs [(the equivalent of 11 to 25 percent spreads)], and 60 to 85 percent below AWP for generic drugs [(the equivalent of 150 to 567 percent spreads)]. *Barron's* also reported that industry insiders joke that AWP really means 'Ain't What's Paid'." (*Id.* at 1-2 (quoting Barron's at 15-16).)
- "The findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies." (*Id.*, Appendix 3, p. 2.)

22. OIG agent Paul Chesser and his colleagues assisted with the 1994 study. Their involvement was as follows:

- In 1994, the OIG identified a random sample of pharmacies in eleven different states. The surveyed pharmacies were classified into categories: chain, independent, or nontraditional. The OIG then asked the states involved in the review to send out a standard letter to those pharmacies. (Tab 7, 06-24-08 Chesser Dep. 156-157; 165; 173-78.)

- They compiled prices from pharmacy invoices to develop a comprehensive, statistically valid measure of the percentage difference between AWP and acquisition cost for virtually all products reimbursed by Medicaid. (Tab 8, 10-28-08 Chesser Dep. 464-469.)

- Mr. Chesser was the contact person for pharmacies participating in the study. As part of that role, he answered questions they had about the study (*id.* at 616) and explained the purpose of the study. (*Id.* at 617.)

23. In November 1994, a publication called *Drug Topics* reported on the HCFA study. (Tab 90, Abbott Ex. 036 11-7-1994, "HCFA Taking Hard Look at Drug Costs," *Drug Topics*.) The article noted that HCFA undertook the study to "develop an estimate of the difference between the actual acquisition cost of [drugs] and the AWP," using data obtained from "48 randomly selected chain and independent pharmacies in 12 randomly selected states." (*Id.*)

24. One of the surveyed pharmacies was Cobo Pharmacy in Key West, Florida—a pharmacy that is owned and operated by Ven-A-Care's then-president Luis Cobo. (*See* Tab 10, 01-18-08 Cobo Dep. 31-32; 103-06; Tab 11, 03-04-08 Cobo Dep. 390-92; Tab 12, 07-31-08 Cobo Dep. 868-69).

25. Bruce Vladeck, Ph.D. was the HCFA Administrator from May 1993 to September 1997 (Tab 59, 05-04-07 Vladeck Dep. 77-78). The HCFA Administrator is responsible for supervising, and is the "top person running, day-to-day, both the Medicare and Medicaid programs." (*Id.* 95; Tab 60, 06-21-07 Vladeck Dep. 393.) He/she reports to the Secretary of the

Department of Health and Human Services, who reports directly to the President of the United States; therefore, the HCFA Administrator is only two steps removed from the President. (Tab 60, 06-21-07 Vladeck Dep. 392-95.)

26. Administrator Vladeck testified that he was aware that AWP was not an actual acquisition cost, and, by the end of his term in 1997, was aware of average discounts for generic drugs of 42.5%, which is a 74% spread under Plaintiff's methodology. (Tab 59, 05-04-07 Vladeck Dep. 213-17; Tab 60, 06-21-07 Vladeck Dep. 497-98; Tab 59, 05-04-07 Vladeck Dep. 229-30.)

- "We did not believe we were paying actual acquisition costs." (Tab 60, 06-21-07 Vladeck Dep. 382.)
- HCFA "knew all along we were overpaying for drugs in the Medicare program" and had information regarding mega-spreads exceeding "500 percent, and in some instances more than 1,000 percent." (*Id.* at 526-27.)
- "[I]n fact, the expectation, the belief about generics, was that it was more likely to be between 25 and 40 percent difference between actual market price and average wholesale price"—an equivalent of 33 and 67 percent spreads, respectively, according to Plaintiffs' formula. (*Id.* at 497-98.)
- By 1997, Vladeck was aware that average discounts for generic drugs were 42.5 percent below AWP, which translates into a spread of 74%. (Tab 59, 05-04-07 Vladeck Dep. 229-30; Tab 60, 06-21-07 Vladeck Dep. 497-98.)

27. In January 1996, the Congressional Budget Office ("CBO") published a report that found that "wholesalers paid on average 80 percent of the [AWP]" for the top-selling Medicaid drugs in 1993. (Tab 91, Dey Ex. 173A at 20, Box 2, Jan. 1996 Congressional Budget Office, *How The Medicaid Rebate On Prescription Drugs Affects Pricing In The Pharmaceutical Industry* (Jan. 1996 CBO Report).) Using AMPs collected by HCFA and AWPs reported in *Redbook*, the Congressional Budget Office compared the relationship between the two figures "to determine the equivalent discount off the AWP that a private purchaser must obtain before

the Medicaid best-price provision applies." (*Id.*) The CBO made the following statements and conclusions:

- "The average wholesale price (AWP) is the published (list) price that manufacturers suggest wholesalers charge their customers. Wholesalers usually charge pharmacists a price that is lower than the AWP, which is the price that is most widely available in published form." (*Id.*)

- "[T]he average manufacturer price (AMP), used to calculate the Medicaid rebate, is not public information. The AMP is lower than the AWP since it is the average price paid by wholesalers." (*Id.*)

- "CBO examined the relationship between the AWP and AMP for 224 drug products that were the top-selling Medicaid drugs in 1993 (based on data collected by the Health Care Financing Administration for the Medicaid rebate program and the AWPs reported in Redbook). For that sample, the AMP averaged 80 percent of the AWP. Therefore, wholesalers paid on average 80 percent of the list price for those drugs. For 84 percent of the 224 drug products examined, the AMP fell between 75 percent and 85 percent of the AWP. For 94 percent of the 224 drug products, the AMP fell between 75 percent and 90 percent of the AWP. Given that the AMP is equal to 80 percent of the AWP on average, a discount of 32 percent off the AWP equals a discount of 15 percent off the AMP on average." (*Id.*)

28. At a February 27, 1996 hearing, Representative Pete Stark of California, the ranking member of the House of Representatives Ways and Means Subcommittee on Health introduced a bill seeking to stop fraud and waste in Medicare payments. In support of the bill, Rep. Stark stated the following:

- "Medicare [is] being defrauded by pharmaceutical companies . . . because AWP . . . is grossly overstating the true price of these drugs to health care providers. . . . The AWP figures reported in such sources as *Drug Topics Red Book*, *American Druggist Blue Book*, or *Medispan* are simply not reflective of what the reimbursed price should be." (Tab 92, Roxane Ex. 30, Feb. 27, 1996, Statement of Congressman Pete Stark in the House of Representatives at 1.)

29. In its May 1996 report, titled "Appropriateness of Medicare Prescription Drug Allowances," the OIG informed HCFA that Medicare could have saved $144 million in 1994 if it had used reimbursement formulas more similar to those used in Medicaid instead of an undiscounted AWP. (Tab 94, Dey Ex. 8, OIG May 1996, "Appropriateness of Medicare

Prescription Drug Allowances," OEI-03-95-00420 ("May 1996 OIG Report").) The OIG also suggested that HCFA could reimburse drugs based on actual acquisition cost. (*Id.* at 11.)

30. In June 1996, *Barron's* published an article entitled "Hooked on Drugs." The article indicated that AWP was not an actual acquisition cost:

- Reported prices for "the top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions." (Tab 95, Hartman Ex. 7, June 10, 1996, Bill Alpert, "Hooked on Drugs," *Barron's* at 15.)
- AWP "really means 'Ain't What's Paid.'" (*Id.*)
- "[D]rug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims"—the equivalent of 150-900% spreads. (*Id.*)
- AWPs "originate with the manufacturer" and "for generic drugs, nearly every manufacturer's price was 60-85% below the published [AWP]," the equivalent of 150-567% spreads, respectively. (*Id.* at 15-16.)
- "[D]rug salespeople . . . let[] the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm." (*Id.* at 16.)
- "If manufacturers deliberately maintain lofty AWPs on their generic drugs . . . the drug makers might then gain market share and higher sales from their customers' over-utilization" (*Id.*)
- "Some of these AWP's actually have risen, while real wholesale prices have plummeted." (*Id.*)
- Medicare and Medicaid "have been paying too much for . . . drugs" because they "generally use AWP as a benchmark for reimbursement." (*Id.* at 16-17.)

31. The *Barron's* article also included quotes and statements indicating that the alleged conduct is fraudulent, and implicates the Anti-Kickback statute and the False Claims Act:

- "[T]he Justice Department is serving 'civil investigative demands' – a kind of subpoena in antitrust investigations – on manufacturers, asking how those inaccurate AWPs wind up in the *Red Book* and *Blue Book*." (*Id.* at 18.)
- An investigator stated that the "drug makers created false statements so that the doctors could make hundreds of millions of dollars" and that "if OIG doesn't get them, the Justice Department will." (*Id.*)

- "Some investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws." (*Id.*)

- "One group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act." (*Id.*)

32. By 1997, the OIG knew that Ven-A-Care was alleging a massive fraud on the Medicaid system. (Tab 57, 02-06-08 Vito Dep. 1224-26.)

33. In January 1997, the *Washington Post* reported that "AWP is not . . . the price that's really charged most customers." (Tab 96, Abbott Ex. 239, Jan. 2, 1997, Spencer Rich, "Battling the High Prices Medicare Pays for Drugs," *The Washington Post*, A15.) The article included the following information:

- "For two years, the General Accounting Office and the Inspector General of the Department of Health and Human Services have bombarded Congress and Medicare program officials with a simple, money-saving message: The prices Medicare pays doctors and drug suppliers for outpatient drugs are too high." (*Id.*)

- "[D]octors can buy drugs from a supplier at less than the AWP, then bill Medicare for the full AWP price. 'They buy at a substantial discount and bill Medicare for a price based on AWP'. . . ." (*Id.*)

- "In order to change the situation, HCFA proposed reimbursing doctors only for the amount they pay for the drugs." (*Id.*)

34. In June 1997, prior to the enactment of the Balanced Budget Act of 1997, the Committee on the Budget of the House of Representatives filed a report, which contained an explanation of why Congress was changing the reimbursement rate for drugs and biologicals. (H.R. Rep. No. 105-149, at 1353-54 (1997), Comm. on the Budget, Report to Accompany H.R. 2015, The Balanced Budget Act of 1997). The report included the following "Reason for Change":

- "The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. For example, the Office of Inspector General reports that Medicare

reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." (*Id.* at 1354.)

35. In December 1997, the OIG published a report comparing drug acquisition prices with Medicare allowances for prescription drugs. (Tab 97, Schering Ex. 5, OIG 1997, *Excessive Medicare Payments for Prescription Drugs* (Dec. 1997 OIG Report).) Using 1995 data on twenty-two of the most commonly-used drug codes, the OIG concluded that "Medicare and its beneficiaries are making excessive payments for prescription drugs." (*Id.* at ii, 2-3.) The OIG recommended to HCFA that it "reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate." It further noted: "We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress [95 percent of AWP] will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities." (*Id.* at iii.) The OIG report further stated and concluded the following:

- "The published AWPs . . . bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." (*Id.* at ii.)

- "HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress." (*Id.* at iii.)

- "Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. For one drug, Medicare allowed 900 percent more than the average price available for the drug in 1995 and 673 percent more in 1996." (*Id.* at 8.)

- "Medicare allowances were also significantly higher than acquisition costs for the remaining 14 drugs reviewed. Medicare allowed 60 to 95 percent more than the actual average wholesale price for 3 drugs in 1995 and 2 drugs in 1996. Medicare allowed amounts were higher by 20 to 50 percent for 9 drugs in 1995 and 8 drugs in 1996. Reimbursement was between 11 and 18 percent more for the remaining 2 drugs in 1995 and 4 drugs in 1996." (*Id.*)

- The OIG included a chart depicting Medicaid reimbursements for seven drugs that each exceeded acquisition costs by over 100 percentage points. (*Id.*)

- "Based on the differences found between Medicare allowed amounts and actual wholesale prices, it is apparent that the current Medicare reimbursement methodology is based on an [sic] significantly inflated AWP statistic which bears little resemblance to actual wholesale prices available in the marketplace." (*Id.* at 9.)

36. HCFA's official response to the 1997 OIG Report acknowledged and concurred with the OIG's findings and recommendations:

- "The findings contained in the report indicate that Medicare is making excessive payments for prescription drugs. The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs." (Tab 97, Schering Ex. 5, Dec. 1997 OIG Report at D-2.)

- "We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways." (*Id.* at D-3.)

37. Robert Vito, who worked in the OIG Office of Audit Services from 1978 through 1990, and who has worked for the Philadelphia office of the OIG Office of Evaluation and Inspections since 1990 (Tab 55, 06-19-07 Vito Dep. 31; 32-33), understood that AWP was not an actual acquisition cost and testified that by 1997, the OIG understood that on average drugs could be obtained at 42.5 percent below AWP. (Tab 56, 02-05-08 Vito Dep. 861-62.) This equates to a spread of 74 percent using Plaintiffs' methodology.

38. By December 1997, David Tawes, current Director of the Medicare and Medicaid Pricing Drug Unit in the Philadelphia office of the OIG Office of Evaluation and Investigations, understood that AWP was not an actual acquisition cost:

- "[T]he AWPs printed in the compendia were not reflective of actual wholesale prices." (Tab 52, 12-13-07 Tawes Dep. 875.)

- The December 1997 report "was intended to communicate to CMS and HCFA that published AWPs were not actual wholesale prices." (*Id.*)

39. Tawes was also aware of Ven-A-Care's allegations by 1997. He testified that by 1997, the OIG had access to catalog pricing from Ven-A-Care, which the OIG used to compile its 1997 reports on excessive drug reimbursement under Medicare and Medicaid. (Tab 51, 4-25-07 Tawes Dep. 385-86; Tab 52, 12-13-07 Tawes Dep. 704.)

40. In a 1997 radio address to the nation, former President Clinton discussed AWP inflation and specifically noted spreads of up to 1000%, "one tenth of the published price." President Clinton stated:

- "[O]ur Medicare program has been systematically overpaying doctors and clinics for prescription drugs . . . Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for drugs. Few doctors however, actually pay the full sticker price. In fact, some pay just one tenth of the published price." (Tab 98, Abbott Ex. 156, 12-13-1997 Radio Address to the Nation.)

- "Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system.... [T]hese overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price, for drugs." (*Id.*)

41. In January 1998, HCFA issued a Program Memorandum, which concluded that AWP is "not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary." (Tab 99, Abbott Ex. 1014, HCFA "Implementation of the New Payment Limit for Drugs and Biologicals," *Program Memorandum Intermediaries/Carriers*, Transmittal No. AB-97-25, Jan. 1998 (1998 Medicare Bulletin).)

42. On March 19 and 20, 1998, Ven-A-Care met with representatives from the majority of state Medicaid programs, the National Association of Medicaid Fraud Control Units ("NAMFCU"), and Nancy-Ann Min DeParle of HCFA, respectively, and presented detailed information about "grossly excessive payments," involving spreads frequently in the hundreds of percents, and up to 3,000%. (Tab 1, 3-6-08 Bentley Dep. 451-54, 597; Tab 33, 12-8-08 Jones Dep. 811-12; (Tab 32, 3-19-08 Jones Dep. 558, 588; Tab 36, 3-17-08 Lockwood Dep. 578.)

Ven-A-Care also described "how the spread was used as a marketing tool, how manufacturers sold their drugs to particular entities using that spread." (Tab 33, 12-8-08 Jones Dep. 810.)

43. Indeed, throughout the 1990s, there was widespread communication between Ven-A-Care and various Governmental individuals regarding reimbursement for pharmaceuticals under the Medicare and Medicaid programs, including the following:

- On June 25, 1996, Zachary Bentley, a Ven-A-Care principal, sent a letter to Keith Lynn at the Senate Finance Committee, stating "Billion dollar & annual loss of the Medicare & Medicaid programs thru fraud & abuse while the DOJ & HHS stand by & watch the thieves 'Rob the Bank'." (Tab 100, Abbott Ex. 571, Summary Exhibit at 1 (excerpted pages due to voluminous document).) Bentley attached the *Barron's* "Hooked on Drugs" article. *Id.*

- On June 12, 1997, Zachary Bentley and T. Mark Jones wrote to HCFA Administrator Dr. Bruce Vladeck, stating that for "the past six years, VAC's officers, directors and legal counsel have made countless telephone calls, written numerous letters, created numerous reports and made detailed presentations to HCFA and other responsible governmental officials detailing the grossly excessive, price gouging reimbursements that the Medicare Program is making . . . ." (*Id.* at 11.)

- On December 3, 1996, Bentley and Jones followed up on the letter to Dr. Vladeck with a letter to Secretary Shalala, informing her that "literally hundreds of millions of dollars" are wasted in "Medicare and Medicaid program funds." (*Id.* at 8.)

44. During this time, Ven-A-Care had also been making presentations to most of the states' governments. (Tab 33, 12-8-08 Jones Dep. 810.) Ven-A-Care's presentations included an allegation that state Medicaid programs have made "excessive reimbursements to providers from 30% to 3000% over the providers' true cost." (Tab 101 at 1, Abbott Ex. 559, Ven-A-Care Texas Presentation.)

45. In 1998, the OIG published a report entitled, "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs." (Tab 102, Lockwood Ery 19, OIG 1998, *Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs* (1998 OIG Report).) In its report, the OIG stated and concluded the following:

- "Because AWP is usually used as a basis for reimbursement at the pharmacy level, manufacturers can use it as a marketing tool to gain market share. For example, by increasing AWP, manufacturers can give pharmacies more Medicaid reimbursement without having to make additional rebate payments. The drug industry currently treats AWP as a published list price rather than a true wholesale price." (*Id.* at 5.)

46. In 1999, the Department of Health and Human Services ("HHS") wrote a report to Congress entitled "The Average Wholesale Price for Drugs Covered under Medicare." (Tab 103 at 8, Abbott Ex. 200, *1999 HHS Report to Congress: The Average Wholesale Price for Drugs Covered under Medicare* (1999 HHS Report).) The report stated and concluded the following:

- AWP "as an unregulated, suggested price, typically set by the manufacturer . . . bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace." (*Id.* at 8.)

- "For the past 13 years, the Office of Inspector General . . . has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than AWP. To address this problem, the President's 1997 budget contained a legislative proposal that would have based payment on the lower of the billed charge or the actual acquisition cost (AAC) for the drug of the physician or supplier billing Medicare. However, as discussed above, in the BBA, Congress rejected this proposal in favor of the current rule, which is to pay based on the lower of the billed charge, or 95 percent of AWP." (*Id.* at 2.)

- There is an average markup for AWP of 41% from the drugs' wholesale catalog price advertised to physicians and suppliers. (*Id.*)

- "AWP is not a well-defined concept nor is it regulated in any way." (*Id.*)

47. On September 1, 1999, Representative Pete Stark of California issued a press release that stated "AWP is a "phony . . . system," a "joke on the taxpayer," and an acronym for "Ain't What's Paid." (Tab 130, 9-1-1999 Stark Press Release, "Drug Utilization Soars as Profits Soar.")

- In 1999, HCFA commissioned a study and report by Myers & Stauffer regarding high-cost drugs under the proposed Outpatient Prospective Payment System. (Tab 105, September 8, 1999, "High Cost Drugs Under the Outpatient Prospective Payment System," Kathal Technologies at 4.) The study reported discounts off of AWP for generic drugs that averaged 58% (a spread of 138%) and climbed as high as 90% (a 900% spread). (*Id.*)

48. Despite the OIG's finding in 1997 that actual acquisition costs for generic drugs were on average 42.5 percent lower than AWP (Tab 89, Roxane Ex. WY 4 at 4, Aug. 1997 OIG Report) as of 1999, the average state discount was 10.4 percent off of AWP. (Tab 106 at 3, Abbott Ex. 121, July 2001 OIG Report, *Cost Containment of Medicaid HIV/AIDS Drug Expenditures* (citing National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Programs," 199, p. 4-57).)

49. In 1999-2000, the House Committee on Commerce conducted a Congressional investigation into reimbursement based on AWP. Hearings were held on the issue, and the OIG sent manufacturers investigation letters. (Tab 107, Abbott Ex. 212, 5-5-00 Rep. Bliley letter to Shalala at 1; Tab 109, Julie Appleby, "House Committee Asks Drug Firms to Justify Pricing Policy," *USA Today*, May 10, 2000, at 1B.)

IV. GOVERNMENT POLICY DECISIONS TO MAINTAIN AWP AND NOT USE ACTUAL ACQUISITION COST AS THE BASIS FOR REIMBURSEMENT: 1992 – 1999

50. The 1991 Medicare regulations provided that reimbursement could be based on AWP or EAC. Any EAC was to be based on carrier surveys of actual provider invoice prices. (56 Fed. Reg. 59502, 59525) HCFA did not pursue surveys of providers' acquisition costs. (Tab 59, 5-4-07 Vladeck Dep. 179-82; Tab 60, 6-21-07 Vladeck Dep. 384.) Although in March 1994, HCFA initially instructed carriers to survey providers' actual acquisition costs, in August 1994, HCFA retracted its instruction and mandated that the carriers "immediately suspend any data collection efforts," because the Office of Management and Budget ("OMB") had not approved the survey. (Tab 108, Abbott Ex. 304, Mar. 22, 1994, Mirabal Letter to All Region II HCFA Medicare Carriers; Tab 110, Abbott Ex. 309, July 25, 1996 Debus Letter to Steffen.) Ultimately, HCFA never undertook the surveys of providers' acquisition costs. (Tab 60, 6-21-07

Vladeck Dep. 384, 386.) As a result, AWP became the default reimbursement methodology for all Medicare claims until January 1, 1998.

51. In February 1996, Representative Pete Stark proposed legislation that would have changed Medicare's payment rate from 100 percent of AWP to 83 percent of AWP. (Tab 92, Roxane Ex. 30, Feb. 27, 1996 Rep. Stark Statement to House of Reps.) Congressman Stark's legislation was never adopted.

52. In 1997 and 1998, as part of the Balanced Budget Acts, the Clinton Administration proposed abandoning an AWP-based reimbursement method altogether and shifting to a system based on actual acquisition costs. Congress rejected the proposals for both years. (Tab 93, Abbott Ex. 213, 5-31-00 Shalala letter to Rep. Bliley; Tab 59, 5-4-07 Vladeck Dep. 178-79; Tab 111, August 2001 Memo from CRS to the House Committee on Energy and Commerce, "Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price" at CRS 6 ("CRS Memo, August 2001").) Congress instead adopted a 5% discount off of AWP such that Medicare Part B drugs were reimbursed at "the lower of 95 percent of the median generic AWP or 95 percent of the lowest brand AWP." (Tab 112, Abbott Ex. 209, 63 Fed. Reg. 58813, 58850 (Nov. 1998)).

53. In 1998, Congress also granted CMS "inherent reasonableness" authority, allowing it to provide guidelines to determine "an amount that is realistic and equitable" when application of Medicare Part B reimbursement rules "results in the determination of an amount that [. . .] is not inherently reasonable." (Tab 111 at CRS-5, CRS Memo, August 2001.) This authority allowed CMS to reduce payment rates by up to 15 percent. (Tab 113, Abbott Ex. 130, BBA § 4316, PL 105-33, 42 U.S.C. § 1395u(b)(8)(B).)

54. Pursuant to its inherent reasonableness authority, in late 1998, HCFA attempted to reduce albuterol payments by 11 percent. (Tab 111 at CRS-5, CRS Memo, August 2001; Tab 114, Abbott Ex. 94, OIG January 2001, *Medicare Reimbursement for Prescription Drugs*, at 2, Appendix F, p. 2 (Jan. 2001 OIG Report).) In 1999, Congress rejected this reduction and suspended HCFA's ability to exercise the inherent reasonableness authority until further investigation was done by the GAO and until the Secretary of the Department of Health and Human Services published final regulations responding to comments received in response to the January interim final regulations. (Tab 111 at CRS-5, CRS Memo, August 2001; Tab 114, Abbott Ex. 94, Jan. 2001 OIG Report, at 2, Appendix F, p. 2; [BBA 1999, § 223, Pub. L. No. 106-113, 113 Stat. 1501A-352-53 (1999); H. Rep. No. 479, 106th Cong. 1st Sess. 876-877 (1999)].)

55. In 1999 and 2000, HCFA submitted a proposal by the President to change Medicare reimbursement to 83 percent of AWP. (Tab 93, Abbott Ex. 213, 5-31-00 Shalala Letter to Rep. Bliley.) Congress rejected the proposal. (Tab 111 at CRS-6, CRS Memo, August 2001.)

56. Dr. Vladeck, HCFA Administrator from 1993 to 1997 (Tab 59, 5-4-07 Vladeck Dep. 77-78), explained that the reason HCFA did not change the reimbursement system was because of political reasons:

- "I think it is fair to say as well that I believed, as – as far back as '95, that 85 percent of average wholesale price as a payment method was inferior to something closer than average acquisition cost, but that the administrative difficulties, and the potential administrative burden on physicians as a political issue, if not a real issue, made it likelier that we would be able to succeed with the legislative proposal still tied to AWP than one that went all the way back to its acquisition costs." (*Id.* 178-179.)

- Urologists, other oncologists, and the American Society of Clinical Oncology strongly opposed proposals to pay less than 100% of AWP and to move away from

AWP as a reimbursement basis. (*Id*. 194; Tab 60, 6-21-07 Vladeck Dep. 326, 333-34, 366.)

- "There are political considerations that, in addition to legal considerations, prevented us from seeking to change the policy administratively. And then there was political opposition to – efforts to change the law itself." (Tab 60, 6-21-07 Vladeck Dep. 379-82.)

57. Thomas Scully, senior White House staff member on health care from 1990-91, and HCFA/CMS Administrator from May 2001 through January 2004, testified that Medicare reimbursement was also affected by politics: "politics is politics and that's what drove this issue for 10 years." (Tab 46, 5-15-07 Scully Dep. 173.)

V. INFORMATION AVAILABLE TO THE GOVERNMENT REGARDING THE DIFFERENCE BETWEEN AWP AND ACTUAL ACQUISITION COSTS: 2000 - 2001

58. A May 2000 *New York Times* article discussing the use of pharmacy benefit management companies to control drug costs quoted a pharmaceutical consultant, who said that AWPs "are not an average, not wholesale, and not a price, other than what employers pay." (Tab 115, May 7, 2000 Milt Freudenheim, "New Questions on Drug Plans as Costs Soar," *New York Times* at 3.)

59. In May 2000, House Commerce Committee Chair Thomas Bliley wrote letters to HHS Secretary Donna Shalala and Administrator Min DeParle requesting that HCFA identify all actions taken by the Administration to investigate and assess the accuracy of AWP. (Tab 107, Abbott Ex. 212, May 2000 Rep. Bliley Letter to Shalala; Tab 116, Abbott Ex. 218, September 2000 Letter to Min DeParle.)

60. On May 31, 2000, Secretary Shalala responded to Rep. Bliley, stating the following:

- By 1998, the OIG knew that payments based on AWP were "11 to 900 percent greater than prices available to the physician community." (Tab 93, Abbott Ex. 213, (5-31-00 Letter. from Shalala to Rep. Bliley, at 2).)

- In 1997 and again in 1998, "President [Clinton] proposed legislation to pay physicians their actual acquisition costs . . . . Unfortunately, Congress did not adopt the Administration's proposal." (*Id.* at 1-2.)

- In 1999 and 2000, the Clinton Administration proposed further discounts off of AWP that Congress rejected. (*Id.* at 2.)

- HCFA planned to utilize data being gathered by the DOJ to make administrative changes to the AWP reimbursement system. (*Id.* at 2.)

61. In August 2000, the *New York Times* reported that while the Clinton administration was planning to decrease Medicare reimbursements, "[a]t least 120 members of Congress . . . have signed letters to Dr. Shalala expressing alarm about the administration's plans." Chris Jennings, health policy coordinator at the White House, noted that "[t]he current reimbursement policy is unsustainable. It's appropriate to reimburse doctors for the cost of the drugs they purchase, but they should not be allowed to mark up the price by 20, 70 or 700 percent, as they do now in some cases." (Tab 117, August 6, 2000 Robert Pear, "Administration Plans Cuts in Some Drug Payments," *New York Times*, p. 2.)

62. In September 2000, Representative Bliley responded to Administrator Min DeParle's May 2000 letter. He criticized the use of the new AWPs that were closer to acquisition cost, citing his concern that it would "impact quality and access to care issues." (Tab 116, Abbott 218, 9-25-00 Letter from Rep. Bliley to Min DeParle.) Rep. Bliley added the following:

- "Echoing the previous findings of numerous reports by the Department of Health and Human Services Office of Inspector General (OIG), the Committee has uncovered substantial evidence that Medicare reimburses health care providers at prices dramatically more than what they actually pay for certain drugs." (*Id.* at 3.)

63. In September 2000, Rep. Stark again issued a press release, alleging "massive abuse of public . . . insurance plans by a number of the nation's major pharmaceutical companies." (Tab 119, 9-27-00 Stark Press Release at 2.)

64. In January 2001, the OIG again recommended that HCFA "reduce excessive Medicare drug reimbursement amounts." (Tab 114, Abbott Ex. 94 at ii, Jan. 2001 OIG Report.) The OIG further stated and concluded the following:

- "Despite numerous attempts by HCFA to lower Medicare drug reimbursement, the findings of this report illustrate once again that Medicare simply pays too much for prescription drugs. The published AWPs that Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers." (*Id.*)

- "The VA paid between 8 and 91 percent less than Medicare for the 24 drugs reviewed." (*Id.* at i-ii.)

65. In September 2001, at a Joint Hearing of the House Subcommittees on Health and Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, "Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers," the following statements were made and testimony was given:

- "[T]he pricing abuses have reached the point at which drug manufacturers use the 'spread' between the AWP and the actual price paid as a marketing took to sell their products. Not only does the taxpayer get gouged; so does the Medicare." (Sept. 2001 Joint Hrg. "Medicare Drug Reimbursements: A Broken system for Patents and "Taxpayers" (107th Cong., 1st Sess., Serial No. 107-65) at 7, Statement of Rep. Peter Deutsch (Sept. 2001 Joint Hrg.).)

- AWPs "aren't the average of anything, they certainly aren't wholesale, and, in fact, they aren't even prices. They are a marketing tool." (*Id.* at 11, Statement of Rep. James Greenwood.)

- "The issue on the table today critically analyzing the marketing practices of drug companies will show the immense amount of fraud perpetrated on the taxpayers and the senior citizens of this country." (*Id.* at 17, Statement of Rep. Frank Pallone.)

- "Unfortunately a lot of manufacturers' representatives are going out and marketing their respective drugs not based on the efficacy of the drug but what in fact will put the most money in either the physician's pocket or the pharmacy's pocket . . . [T]here's marketing actually going on to encourage the utilization of one drug over a competing drug by using government funds that fund the kickback as a marketing mechanism." (*Id.* at 78, Testimony of Zachary Bentley, President of Ven-A-Care, Inc.)

VI. GOVERNMENT POLICY DECISIONS: 2000 – 2001

66. In May 2000, the DOJ proposed reductions in Medicare payments by sending to HCFA and First DataBank revised AWPs for 32 Medicare drugs that were significantly lower than published AWPs. (Tab 118, Roxane Ex. 113 at 1, Sept. 8, 2000 HCFA Program Memorandum Intermediaries/Carriers, "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program," HCFA-Pub. 60AB (9-8-00 HCFA Program Memorandum) (Tab 111 at CRS-6, CRS Memo, August 2001.)

67. In July 2000, Congress resoundingly rejected HCFA's proposal, criticized the Administration's attempt to "redefin[e]" AWP by using amounts reflective of actual average acquisition costs, and reiterated that it intended to maintain a definition of AWP as "amounts reflected in specified publications," i.e., the list price published in compendia such as First DataBank. (Tab 120, Abbott Ex. 220 at 1-2, 7-28-00 Letter from 91 members of Congress to Shalala.) A letter signed by over 90 Congressmen specifically stated that the 1997 BBA authorized HCFA to pay based on AWPs, which were commonly known as the list prices in RedBook and other compendia, rather than the DOJ's revised AWPs that reflected acquisition costs:

- "It is important to recall that reimbursement for cancer drugs is an issue that has been repeatedly addressed by Congress over the past few years in order to respond to various Administration efforts to reduce reimbursement. Thus, Congress in 1997 instructed the Department to base reimbursement for drugs on 95% of AWP, a term widely understood and indeed defined by Department manuals to reference amounts reflected in specified publications. Later, Congress pegged reimbursement for drugs in the hospital outpatient setting to the same definition of AWP." (*Id.* at 1.)

- "It is disturbing that the Department would now seek to circumvent those congressional actions by redefining AWP. We see no basis for such action in any of our previous legislation, and certainly the Department's unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate." (*Id.* at 1-2.)

68. Thus, by 2000, Congress had explicit knowledge of inflated AWPs, yet advocated against utilizing the more accurate data compiled by the DOJ.

69. Despite Congress's voiced opposition, in September 2000, HCFA authorized its carriers to revise downward their AWPS based on the DOJ AWPs and asked program participants to consider them, but did not require either Medicare or Medicaid programs to use the revised AWPs. (Tab 118, Roxane Ex. 113, at 1, 9-8-00 HCFA Program Memorandum.) Medicare carriers did not use the revised AWPs. (Tab 121, Abbott Ex. 221, at 1, 11-17-00 HCFA Program Memorandum.) Many states did not use the revised AWPs. (Tab 122, Abbott Ex. 95, OIG Sept. 2001, *Medicaid's Use of Revised Average Wholesale Prices*.) The Program Memorandum discussed the following:

- The Clinton Administration proposed to reimburse Medicare drugs based on "actual average wholesale prices" that the DOJ and National Association of Medicaid Fraud Control Units ("NAMFCU") had compiled, to counteract mega-spreads. (Tab 118, Roxane Ex. 113, at 1.)

- The DOJ AWPs were "more accurate wholesale prices for these drugs [and that] because purchasers often receive further discounts below the advertised wholesale catalog price . . . actual acquisition costs may be lower." (*Id.* at 1.)

70. At the same time, HCFA Administrator Nancy Min DeParle submitted a letter to Congress explaining her decision. (Tab 123, Abbott Ex. 215, 9-8-00 Ltr. from Min DeParle to Members of Congress.) Her letter stated and concluded the following:

- "[T]he Balanced Budget Act reduced Medicare payments for covered drugs from 100 percent to 95 percent of the average wholesale price. This policy captures only a small fraction of the excessive Medicare payment amounts, as average wholesale price data do not reflect actual costs for many Medicare-covered drugs. Therefore, the Administration has proposed to pay 83 percent of the average wholesale price." (*Id.* at 2.)

- "As we suggested in May, the right approach to addressing Medicare profits on drugs identified by DOJ is to pay correctly for the drugs, and at the same time make changes, as necessary, to assure that Medicare adequately pays for services related to the provision of the drugs." (*Id.*)

71. Within a few months after the DOJ AWPs were provided to Medicaid programs and to Medicare, Congress forbade even the consideration of these revised AWPs. By November 2000, they were withdrawn. In a Program Memorandum dated November 17, 2000, HCFA informed Medicare carriers that they should not use the DOJ AWPs (Tab 121, Abbott Ex. 221, 11-17-00 HCFA Program Memorandum):

- "This is to notify you that you should NOT use the Department of Justice (DOJ) data attached to PM AB-00-86 in your next update of Medicare payment allowances for drugs and biologicals. Instead, until further notice, you should delay use of this new source of average wholesale price (AWP) and use the AWP data from your usual source." (*Id.*)

- "While we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source. To avoid the disruption that would result from a decrease in payment allowances followed by an immediate increase due to final congressional action, we are deferring use of the DOJ AWP data until further notice." (*Id.*)

72. At Congress's direction, HCFA's efforts to decrease reimbursement were once again frustrated. In its comments to the Jan. 2001 OIG Report, HCFA noted "[a]s you know, when we have taken administrative action to reduce payments in the past, we have been blocked by Congress." (Tab 114, Abbott Ex. 94, Jan. 2001 OIG Report, Appendix F, p. 2.)

73. On December 21, 2000, Congress passed legislation that prohibited HCFA from using the DOJ AWPs until GAO completed a comprehensive drug pricing study. (*Id.* at 3.)

VII. FEDERAL GOVERNMENT CONTINUES TO USE AND APPROVE AWP AS A BASIS FOR REIMBURSEMENT

74. The Federal Government continued to use AWP as a basis for reimbursement under Medicare until 2003 when Congress enacted the Medicare Modernization Act (MMA) and changed Medicare reimbursement from AWP-based payments to 106% of the manufacturer's average sales price (ASP). (Medicare Modernization Act of 2003, Pub. L. 108-173,117 Stat. 2066, 2239.)

75. Even though the Federal Government changed the Medicare reimbursement system, it continues to this day to allow most state Medicaid programs to use EAC formulas of AWP minus only a small percentage. (Tab 124, Abbott Ex. 326, 1990 Medicaid Drug Reimbursement Report.)

76. CMS also continued to approve state plan amendments ("SPA") that proposed AWP-based formulas that would result in payments higher than actual acquisition costs. For example, HCFA approved a 2002 Kentucky SPA to change reimbursement from AWP-10% to AWP-12% despite Kentucky supporting its submission with a Myers & Stauffer report showing that pharmacies acquired multi-source drugs at AWP-34.1% (without a FUL) to 81.4% (with a FUL). (Tab 125, HHD087-3742 - 3790, Aug. 12, 2002 CMS Letter Approving Kentucky State Plan Amendment 02-04 and Accompanying Documents.)

77. As Deirdre Duzor, the Director of CMS's Medicaid Pharmacy Division, testified, CMS continued to approve state plan amendments that reimbursed at AWP-20% despite its awareness that average acquisition cost for generics was AWP-60%:

> Q. Okay. I will rephrase the question. If, in fact, you have reports from the OIG indicating that generic drugs are available at AWP minus 60 percent on average across the board for all generics, why do you approve plans that allow reimbursement for generics at AWP minus 15 or minus 20?
>
> * * *
>
> THE WITNESS: Because they're moving in the right direction. They're reducing pharmacy reimbursement and saving the states and the federal government money by doing so.
>
> BY MR. MERKL: Q. So you are aware, then, that the pharmacies are making money on that difference between what they're acquiring the drug for and what they're reimbursing it at in the case of generics?
>
> * * *

> THE WITNESS: Yes. Based upon the OIG reports, we are aware of that.

(Tab 21, 3-26-08 Duzor Dep. 645-47.)

78. In addition, once CMS approves a state plan, the state plan remains in effect and CMS does not review it again "until the state chooses to change its state plan." (Tab 48, 3-27-08 Smith Dep. 515-18.)

79. Moreover, in its 2008 report, "Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs," OIG concluded that pharmacies' acquisition costs of generic drugs were AWP-73%. (Tab 126, OIG Jan. 2008, "Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs," A-06-07-00107, Table 2, at 6 ("Jan. 2008 OIG Report").) Under Plaintiffs' methodology, this translates to a 270% spread. CMS responded to the report:

- Although CMS indicated that it understood that the OIG report "found that the **percentage differences between Part D payments and drug acquisition costs** were more than **nine times higher** for generic drugs than for brand-name drugs," it **"fully encourage[d]** the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and we note that incentives are aligned to encourage the promotion of generics by community pharmacies." (*Id.* at Appendix G, p. 1 (emphasis added).)

VIII. INFORMATION REGARDING WIDESPREAD DISCOUNTS OFF AWP: IPRATROPIUM BROMIDE AND NEBULIZER DRUGS

80. In February 1996, the OIG published a report concerning the extent to which Medicare was overpaying for three nebulizer products, similar to Albuterol Sulphate and ipratropium bromide. (Tab 127, Abbott Ex. 33, OIG Feb. 1996, *Medicare Payments for Nebulizer Drugs* (Feb. 1996 OIG Report).) In its report, the OIG stated and concluded the following:

- "Medicare allowed a higher price to drug suppliers for two of the three drugs reviewed because of the manner in which it used the AWP to determine the drug price." At the time, Medicare was still using the full, undiscounted, published AWP as the basis for calculating provider reimbursement. (*Id*. 2, 6.)

- OIG recommended that "HCFA reexamine its Medicare drug reimbursement methodologies with a goal of reducing payments as appropriate." (*Id.* 11.)

- Had Medicare reimbursed providers based on a discounted AWP—as twenty-six state Medicaid programs were already doing—Medicare would have saved millions of dollars. (*Id*. 13.)

81. David Tawes, Director of the Medicare and Medicaid Drug Pricing Unit in the Philadelphia office of the OIG Office of Evaluation and Investigations, was aware of spreads on ipratropium bromide:

- Among the catalog prices reported by Ven-A-Care in 1997, the OIG received prices for ipratropium bromide. (Tab 52, 12-13-07 Tawes Dep. 707; Tab 128, Roxane Ex. 17, Conversion from NDC Amounts to HCPCS Amounts.)

- The OIG considered including ipratropium bromide in its 1997 report on excessive drug reimbursement, and documents show that at that time the OIG performed calculations to determine the spreads between the Ven-A-Care prices and the amounts being reimbursed by Medicare. (Tab 52, 12-13-07 Tawes Dep. 697; Tab 128, Roxane Ex. 17, Conversion from NDC Amounts to HCPCS Amounts.)

82. Based on information that albuterol payments under Medicare were substantially higher than acquisition costs, in 1998 HCFA attempted to use its inherent reasonableness authority to reduce payments for albuterol by 11 percent. Congress rejected the reduction and also suspended the inherent reasonableness authority in 1999 until further investigation by the GAO. (Tab 111 at CRS-5, CRS Memo, August 2001; Tab 114, Abbott Ex. 94, Jan. 2001 OIG Report, *Medicare Reimbursement for Prescription Drugs*, at 2, Appendix F, p. 2.)

83. In November 1998, the OIG issued a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs." In its report, the OIG stated and concluded the following:

- AWPs for ipratropium bromide were, on average, 155% higher than the prices at which that drug could be purchased by government providers. (Tab 129, Roxane Ex. 159, OIG Nov. 1998, *Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs* 7, 13. (Nov. 1998 OIG Report.)

84. By 1998, OIG Regional Inspector General Robert Vito was "aware that ipratropium bromide represented potential savings to the Medicare program." (Tab 58, 12-2-08 Vito Dep. 1295-96.)

85. Representative Stark's September 1999 press release, "Drug Utilization Soars as Profits Soar," also included the following statements and conclusions specific to ipratropium bromide:

- "In the last several years, the cost of ipratropium bromide to druggists and doctors has dropped by 50%, but the amount per unit that Medicare pays for this drug has stayed the same." (Tab 130, 9-1-99 Stark Press Release "Drug Utilization Soars as Profits Soar" (9-1-99 Stark Press Release).)

- A table comparing the average Medicare reimbursement for ipratropium bromide with the cost to the wholesaler for that drug for the years 1996 to 1999 showed that the spreads for ipratropium bromide increased progressively and dramatically over the years as follows: 15% in 1996; 63% in 1997; 96% in 1998; and 10% in 1999. (*Id*.)

86. The OIG obtained pricing information related to ipratropium bromide from Ven-A-Care by early 2001 that it used to compile its 2001 report on ipratropium bromide. (Tab 58, 12-2-08 Vito Dep. 1315.)

87. In September 2001, the United States General Accounting Office ("GAO") issued a report to Congress entitled "Payment for Covered Outpatient Drugs Exceed Providers' Costs." (Tab 131, Abbott Ex. 186, Sept. 2001 GAO Report). The report, which was commissioned by Congress, examined revised prescription drug reimbursement methodologies under Medicare and Medicaid. In its report, the GAO stated and concluded the following:

- "[T]wo drugs used with durable medical equipment had discounts of 78% and 85%, equating to 'spreads' of 355% and 567%." *In re Pharm. Indus. AWP Litig*., 491 F.

Supp. 2d at 43 (citing Report to Congressional Committees, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost 2001 ("GAO Report"), at 4).

- The drug with the 78% discount and the 355% spread was ipratropium bromide. (*Id.* 4.)

88. Former HCFA/CMS Administrator Thomas A. Scully was aware of "mind blowingly big margins" for ipratropium bromide. (Tab 46, 5-15-07 Scully Dep. 255.)

89. In March 2002, the OIG issued a report to CMS entitled *Excessive Medicare Reimbursement for Ipratropium Bromide*. (Tab 132, Roxane Ex. 1, 2002 OIG Report, *Excessive Medicare Reimbursement for Ipratropium Bromide*, (Mar. 2002 OIG Report).) In its report, the OIG specifically noted CMS's "numerous attempts" to "lower reimbursement amounts for prescription drugs," and stated that its findings "illustrate that Medicare pays too much for ipratropium bromide." (*Id.* at iii.) The report also noted that the OIG understood that "unlike most drugs covered by Medicare, ipratropium bromide is usually provided by suppliers rather than administered by physicians. *These suppliers obviously need to make a profit* from the products they provide, yet the spread between what Medicare reimburses for ipratropium bromide and the price at which suppliers are able to purchase the drug is significant." (*Id.* (emphasis added).) Compared to drugs purchased form wholesalers, this translates to a spread of 300 percent under Plaintiffs' methodology. (*Id.* at 19.)

90. In 1996, Ven-A-Care began tracking prices of ipratropium bromide and Albuterol. (Tab 133, Roxane Ex. 90, p. 45 (IB Chart)); (Tab 34, 12-9-08 Jones 30(b)(6) Dep. 1140-45.) Dey and Roxane were the sole manufacturers of generic Iptratropium Bromide from 1996 through the late 1990s. (Tab 34, 12-9-08 Jones 30(b)(6) Dep. 1144-45.)

IX. THE GOVERNMENT RECEIVED A WORKING DATABASE THAT SHOWED THE "SPREADS" FOR ALL OF ROXANE'S DRUGS

91. Ven-A-Care also provided the federal Government with a working database provided by the McKesson wholesaler called Econolink that included the regular and contract prices for every Roxane NDC drug at issue in this case (except the Novaplus ipratropium bromide NDCs). (Tab 38, 6-19-09 Lockwood Dep. 95-96.)

92. The Econolink database was accessible to McKesson's customers, including Ven-A-Care. (*Id.* 18-21.)

93. In addition to the working database on the laptop computer, Ven-A-Care provided eleven updates, or database "snapshots" from the Econolink database to the Government, on the following dates: October 23, 2000; December 12, 2000; February 22, 2001; April 20, 2001; June 19, 2001; August 9, 2001; November 12, 2001; January 28, 2002; March 10, 2002; May 8, 2002; and June 25, 2002. (Tab 38, 6-19-09 Lockwood Dep. 15-16, 24-27, 31; Tab 134, Roxane Ex. 226, October 23, 2000 Econolink short-form printout; Tab 135, Roxane Ex. 231, December 12, 2000 Econolink short-form printout; *see also* Tab 136, Roxane Ex. 223, Feb. 24, 2009 e-mail from Alison Simon to Eric Gortner re McKesson Econolink databases.)

94. The Econolink database contained pricing data for NDCs, including AWP, the wholesaler price, and any contract price that applied. (Tab 38, 6-19-09 Lockwood Dep. 19.) In addition, it "would automatically calculate what it termed the spread"—it "actually . . . would show you the spread and it was labeled spread between the AWP and the acquisition cost that was calculated by the software." (Tab 38, 6-19-09 Lockwood Dep. 78-79; Tab 37, 7-23-08 Lockwood Dep. 1109, 1120.)

95. Prior to 2001, the database showed spreads of over 100%, and in several cases over 1,000%, for all of Roxane's drugs at issue in this case. (Tab 38, 6-19-09 Lockwood Dep.

90-95.) For example, the short form printout of Roxane drugs in the Econolink database from December 12, 2000, showed the following range of spreads, as calculated under Plaintiffs' methodology for the nine drugs at issue here:

- Oramorph NDC 00054-4790-29: AWP of $413.20 and a contract price of $198.74—a **spread of 108%**
- Roxicodone NDC 00054-4657-25: AWP of $31.04 and a contract price of $13.44—a **spread of 131%**
- Azathioprine NDC 00054-4084-25: AWP of $131.08 and a contract price of $43.72—a **spread of 200%**
- Hydromorphone NDC 00054-8394-24: AWP of $71.71 and a contract price of $22.58—a **spread of 218%**
- Sodium Polystyrene NDC 00054-8816-11: AWP of $86.50 and a contract price of $25.56—a **spread of 283%**
- Ipratropium bromide NDC 00054-8402-13: AWP of $52.80 and a contract price of $10.86—a **spread of 386%**
- Roxanol NDC 00054-3751-50: AWP of $77.96 and a contract price of $11.72—a **spread of 565%**
- Diclofenac Sodium NDC 00054-4222-31: AWP of $1,025.25 and a contract price of $152.19—a **spread of 574%**
- Furosemide NDC 00054-4297-31: AWP of $139.90 and a contract price of $8.84—a **spread of 1,483%**

(Tab 135, Roxane Ex. 231, December 12, 2000 Econolink short-form printout.)

X. GENERAL ROXANE BACKGROUND

96. In April 2005, Roxane Laboratories, Inc., a Delaware corporation, changed its name to Boehringer Ingelheim Roxane, Inc. ("BIRI"). (Roxane Answer to First Am. Compl. at 1 n.1) BIRI remains a Delaware corporation. (*Id.*) BIRI continues to manufacture pharmaceutical products. (*Id.*) Also in April 2005, a new entity, Roxane Laboratories, Inc., a Nevada corporation, was incorporated. (*Id.*) As of that time, the new Nevada corporation ("Roxane

Nevada") assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane tradename. (*Id.*) For the purpose of this Statement of Facts, all statements referencing "Roxane" will be meant to reference the company BIRI for the time period until April 2005 and Roxane Nevada for the time period after April 2005.

97. Roxane has been a manufacturer and seller of predominantly generic pharmaceuticals in the United States. (Tab 65, 5-9-07 Waterer Dep. 36; Tab 14, 5-30-07 DeCapua Dep. 15-16) Currently, the Roxane product line consists of roughly 400-500 NDCs. (Tab 14, 5-30-07 DeCapua Dep. 167)

98. Roxane's products are almost all self-administered drugs, taken by the patient in tablet, capsule, or liquid form, including the drugs at issue in this case. (Tab 65, 5-9-07 Waterer Dep. 36-37; Tab 5, 12-12-08 Carr-Hall Dep. 53; Tab 41, 3-8-05 Paoletti Dep. 474; Tab 137, United States' First Am. Compl. Ex. A)

XI. ROXANE'S UNDERSTANDING OF AND PRACTICES REGARDING AWP

99. Roxane understood AWP to be a reference point that is generally tied to the branded version of a multisource drug. (Tab 65, 5-9-07 Waterer Dep. 69, 93-94) At launch AWP is generally set at 10% below the corresponding brand's AWP. (*Id.*) Roxane understood this to be the industry standard. (Tab 65, 5-11-07 Waterer Dep. 604; Tab 66, 12-12-08 Waterer Dep. 33-34)

100. Roxane's understanding of the industry standard came from (1) general common knowledge, (2) publicly-available information such as the AWPs of Roxane's competitors, and (3) Roxane employee's contacts with everyone in the industry that they worked with. (Tab 66, 12-12-08 Waterer Dep. 27-28, 38-40)

101. Roxane never intended its AWPs to be used as or to represent an actual average of wholesale prices to customers, as that was not the meaning of AWP as used in the industry. (*Id.*)

24-25) Roxane's AWPs also did not bear a predictable relationship to the prices that Roxane's drugs were sold in the marketplace, and nobody in the industry thought that they did. (*Id.* 26-28 ("(W)e've never heard it described as anything else. In many, many, many years in the industry, it's been AWP has had a recognized definition or meaning that did not mean it was an actual, some kind of calculated average of prices in the marketplace …. ")

102. As the Government was an important participant in the industry, Roxane had no reason to believe that it did not have the same understanding of AWP as everyone else in the industry. (*Id.* 33-34) On the contrary, Roxane had every reason to believe that the government knew very well that AWP was not a defined actual average wholesale price, based the following facts:

- AWP is a generally understood term in the industry in which the Government participates. (*Id.* 137-39 ("the government would have every reason to know that that price was not defined in the industry or in any general practice as some kind of an actual average of wholesale prices.”))

- Roxane provides the federal government with Average Manufacturer Prices ("AMPs") for its products and the Government can easily see the difference between the AWPs published for its products and the AMPs Roxane provides. (*Id.* 172-73) (discussed more fully below)

- Roxane understood that to the extent the government and other third party payors tied reimbursement to AWP, it was always set at a discount off of AWP. Roxane believed those discounts ranged from 10 to 40 percent off of AWP. Thus the Government and third party payors could not have believed AWP was an actual acquisition cost. (*Id.* 28-29 ("it would be irrational to think that anybody doing that reimbursement would think that's the price that a customer paid for it, that they would be willing to accept reimbursement way below what their acquisition cost was”))

- Roxane and other manufacturers generally set their AWPs when a product launched; a time when there was no historical pricing or sales off of which an average of actual wholesale prices could be calculated and reported. (*Id.* 236-37)

- Historically, when the Government has wanted an average or a specific number calculated and reported, it generally provides a formula and guidance on how to calculate that figure, as it did with AMP and ASP. Otherwise, without such guidance, there are too many variables and questions about what should be

included and how the figure should be calculated. The Government has never provided a formula or guidance on how to calculate AWP. (*Id.* 145)

103. Roxane does ***not*** have an understanding that Medicaid programs seek to determine and estimate an acquisition cost as part of their reimbursement for reimbursing pharmacists. (*Id.* 30)

104. Roxane provides AWPs to the pricing compendia, such as First DataBank, because its pharmacy customers require it. (Tab 65, 5-9-07 Waterer Dep. 63-64)

105. If Roxane is late to the market and there are many other generic competitors, Roxane may set its AWP at launch at or around the same level of the generic competitors instead of at the brand AWP minus 10%. (Tab 66, 12-12-08 Waterer Dep. 41-42)

106. After Roxane sets an AWP for a drug, it generally does not change its AWP. Roxane understood that industry practice for generic products was that after launch the AWP was not typically changed. (*Id.* 94-95) Two exceptions to this rule are: (1) when a Roxane drug becomes a sole-source drug, Roxane may increase all of its prices across the board, including the AWP; and (2) when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. (Tab 65, 5-9-07 Waterer Dep. 74-76)

XII. ROXANE'S UNDERSTANDING OF AND PRACTICES REGARDING WAC

107. Roxane's WAC was not a net number; rather it was a list invoice price that Roxane charged wholesalers. (Tab 65, 5-9-07 Waterer Dep. 72-73) Roxane believed this to be the industry understanding and practice regarding WAC. (Tab 65, 5-11-07 Waterer Dep. 660)

108. Federal government reports as early as 1994 confirmed the Federal government's acknowledgment of this industry understanding that WAC does not include prompt pay or other discounts, rebates, or reductions in price. (Tab 88, U.S. Gen. Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom,*

Jan. 1994) (confirming that, in 1994, it was generally understood that WAC does not capture manufacturers' discounts and price reductions to certain buyers)) Congress codified this industry understanding in the Medicare Modernization Act of 2003 where WAC is defined as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price …." (42 U.S.C. § 1395w-3a(c)(6)(B))

109. Roxane set the WACs for its drugs in accordance with this industry standard as the list or invoice price that a wholesaler pays Roxane. (Tab 65, 5-11-07 Waterer Dep. 615-16) This amount initially invoiced by Roxane may be reduced for a particular wholesaler if the wholesaler qualifies for a prompt pay discount (typically 2%) or other occasional discounts such as an additional discount when a new product is launched. (*Id*. 616-17; Tab 62, 10-24-01 Waterer Dep. 178)

110. The amount ultimately paid by a particular wholesaler to Roxane will also depend on whether Roxane has a pre-negotiated contract price with the provider purchasing the drug from the wholesaler. This contract price is generally lower than WAC. (Tab 65, 5-9-07 Waterer 150-51) If Roxane does not have a pre-negotiated contract price with the provider, then the wholesaler sells the product to the provider at a price that, presumably, covers its costs, but Roxane does not know prices charged by wholesalers. (Tab 65, 5-11-07 Waterer Dep. 577-80, 593-95; Tab 65, 5-9-07 Waterer Dep. 84-86) If Roxane negotiated a contract price with the provider purchasing the product from the wholesaler, then the provider pays the wholesaler this contract price plus any markup charged by the wholesaler. (Tab 65, 5-11-07 Waterer Dep. 577-80; Tab 65, 5-9-07 Waterer Dep. 84-86) Because the price paid by the provider is less than the price at which the wholesaler purchased the product from Roxane, Roxane pays the

wholesaler a "chargeback" to make the wholesaler whole. (Tab 65, 5-11-07 Waterer Dep. 577-80, 593-95; Tab 65, 5-9-07 Waterer Dep. 84-86)

111. There is no set formula that Roxane uses to set its WACs; rather it sets its WACs on a case-by-case basis based on market conditions. (Tab 65, 05-09-07 Waterer Dep. 71-72; Tab 65, 05-11-2007 Waterer Dep. 627-30) If Roxane's product was the only generic in the market, it would typically set WAC at 20% less than AWP, similar to how branded products set WAC. (*Id.*) If the generic market Roxane entered was already competitive, Roxane would typically set WAC at a greater percentage off of WAC. (*Id.*)

XIII. ROXANE'S PRICE REPORTING PRACTICES

112. Roxane provided AWPs to pricing compendia such as First DataBank and Red Book for the multi-source generic drugs at issue. (Tab 65, 5-9-07 Waterer Dep. 68; Tab 63, 4-1-03 Waterer Dep. 502) Roxane stopped reporting AWP for its branded products when it divested those products in 2001. *See* Section IX [Divestment], *supra*.

113. Up until late 1997 or early 1998, Roxane also supplied WAC prices to the pricing compendia for the all drugs at issue. (*Id.*) However, Roxane stopped providing WACs for its multi-source generic products to the pricing compendia — including the (furosemide, azathioprine, diclofenac sodium, hydromorphone, and ipratropium bromide NDCs that are at issue in this case) — in late 1997/early 1998. (*Id.*) Instead Roxane opted to supply WAC prices directly to its customers and to state and federal government agencies upon request. (Tab 65, 5-11-07 Waterer Dep. 666-69) Roxane continued to provide WAC for its branded and branded generic products, including for the Roxanol, Roxicodone and Oramorph SR NDCs at issue in this case, after 1998 and until 2001 when it divested the products. (Tab 9, 7-25-07 Ciarelli Dep. 49-52)

114. Roxane stopped reporting WAC for its multisource products in late 1997 or early 1998 because it was not industry custom in the generic market to report WAC. (Tab 42, 7-26-07 Paoletti Dep. 179-82) Roxane did not want to publicly publish WAC because it was and is an actual transaction price for its drugs. (*Id.*; Tab 63, 4-1-03 Waterer Dep. 471-72)

115. Starting in 2004, Roxane began reporting an Average Sales Price ("ASP") to CMS pursuant to the Medicare Modernization Act of 2003. (Tab 138, 42 U.S.C. § 1396r-8(b)(3))

XIV. FULs FOR ROXANE'S DRUGS AT ISSUE

116. In 1987, the federal government adopted the Federal Upper Limit ("FUL") program to allow States to benefit from steep discounts in the generic market by encouraging migration to lower-cost generic drugs. (42 C.F.R. §§ 447.331, 447.332 *et seq.*)

117. The FUL program was intended to "enable[] the Federal and State governments to take advantage of savings that are … available in the marketplace for multiple source drugs" while at the same time maintaining flexibility for States to determine their own reimbursement rates and to experiment with methods of further controlling the cost of offering Medicaid beneficiaries a prescription drug benefit. (Tab 83, 52 Fed. Reg. 28648 (July 31, 1987)) The FUL regulation provides that a State's reimbursement for multiple source drugs "in the aggregate" must not exceed 150% of the lowest published price for the least costly therapeutically equivalent product where at least three suppliers market a given generic drug. (42 C.F.R. § 447.332) CMS generally looks to ensure that there are at least two A-rated drugs in the FDA's Orange Book, or, if there is a B-rated drug, three A-rated drugs when establishing a FUL. (Tab 26, 1-24-08 Gaston Dep. 56)

118. To establish FULs, HCFA relied on an automated system that used drug and pricing data to compile an initial list of drugs and FULs. (*Id.* 232-34) Then HCFA engaged in a

"manual review" of the initial list whereby HCFA employees would often adjust FULs in order to "make sure that the FUL price that's set is a reasonable price and that we'll be assured the availability of the drug." (Tab 27, 3-19-08 Gaston Dep. 442-45) HCFA set FULs that it believed could both achieve cost-savings and provide sufficient access to care such that providers could actually acquire drugs at the FUL price. (*Id.* 428-29, 498-99) HCFA acknowledged that it was "building into [FUL] rates for ingredients a profit margin for pharmacists." (Tab 83 Abbott Ex. 284, 52 Fed. Reg. 147, 28656 (July 31, 1987)) In some cases, CMS will decline to set a FUL for that specific drug if drugs are not likely to be available at the FUL price or there will not be a cost savings to states by establishing a FUL. (Tab 27, 3-19-08 Gaston Dep. 451)

119. The FUL regulation did not establish a reimbursement rate for any drug, but afforded States flexibility in setting reimbursement rates for particular drugs so long as the state reimburses at or below the applicable FUL limitation. (42 C.F.R. §§ 447.304, 447.331-334)

120. The FULs set by CMS for Roxane's subject drugs are as follows:

Drug Name	**NDC**	**FUL**	**Begin Date**	**End Date**
Furosemide 10mg/ml solution, 60s	00054-3294-46	$.1142	July 1, 1997	March 31, 2000
		$.1300	April 1, 2000	Present
Furosemide 10mg/ml solution, 120s	00054-3294-50	$.1249	July 1, 1997	July 1, 1998
		$.0893	April 1, 2000	November 19, 2001
Furosemide 20mg tablet, 100s	00054-4297-25	$.0158	July 1, 1990	September 30, 1992
		$.0189	October 1, 1992	April 30, 1994
		$0203 from May 1, 1994	October 31, 1996	October 31, 1996
		$.021	November 1, 1996	March 31, 2000

Drug Name	NDC	FUL	Begin Date	End Date
		$.042	April 1, 2000	November 19, 2001
		$.0453	November 20, 2001	March 4, 2002
		$0.563	March 5, 2002	Present
Furosemide 40mg tablet, 100s	00054-4299-25	$.0173	July 1, 1990	September 30, 1992
		$.0222	October 1, 1992	September 30, 1993
		$.0251	October 1, 1993	September 30, 1994
		$.027	October 1, 1994	May 30, 1996
		$.0248	June 1, 1996	October 31, 1996
		$.0254	November 1, 1996	March 31, 2000
		$.044	April 1, 2000	November 19, 2001
		$.0522	November 20, 2001	March 4, 2002
		$.0599	March 5, 2002	Present
Furosemide 80mg tablet, 100s	00054-4301-25	$.045	July 1, 1990	September 30, 1992
		$.053	October 1, 1992	September 30, 1993
		$.0525	October 1, 1993	April 30, 1994
		$.0531	May 1, 1994	September 30, 1994
		$.0563	October 1, 1994	June 30, 1997
		$.0473	July 1, 1997	March 31, 2000
		$.071	April 1, 2000	November 19, 2001
		$.0915	November 20, 2001	March 10, 2003
		$.1043	March 11, 2003	Present

Drug Name	NDC	FUL	Begin Date	End Date
Diclofenac Sodium 50mg tablet, 100s	00054-4221-25	$.8375	June 1, 1996	October 31, 1996
		$.8544	November 1, 1996	June 30, 1997
		$.8285	July 1, 1997	July 1, 1998
		$.749	July 2, 1998	March 31, 2000
		$.4748	April 1, 2000	Present
Diclofenac Sodium 75mg tablet, 100s	00054-4222-25	$1.014	June 1, 1996	October 31, 1996
		$.9647	November 1, 1996	June 30, 1997
		$.9219	July 1, 1997	March 31, 2000
		$.656	April 1, 2000	November 19, 2001
		$.585	November 20, 2001	Present
Ipratropium Bromide .02% Solution for Inhalation, 2.5ml, 25s	00054-8402-11	$.303	August 24, 2003	November 1, 2003
		$.234	November 2, 2003	February 13, 2005
		$.108	February 14, 2005	Present

(Tab 139, 11-21-08 United States' Objections and Supplemental Response to Interrogatory No. 7, served at 13-14)

121. However, CMS did not always set FULs for certain drugs that were statutorily eligible for a FUL. (Tab 140, Abbott Ex. 108 at 6, OIG Feb. 2004, *Omission of Drugs from the Federal Upper Limit List in 2001*, (OEI-03-02-00670) (Feb. 2004 OIG Report)) ("Medicaid could have saved $123 million in 2001 by adding 55 drug products to the Federal Upper Limit list. This represents 30 percent of the $411 million Medicaid reimbursed for the 55 products that year. Each of these drug products had at least three versions rated therapeutically equivalent by FDA and were available from three or more suppliers.")

122. The OIG specifically noted that ipratropium bromide, a drug at issue in this Action, was one of "(f)our drug products [(that)] accounted for 71 percent of the $123 million in potential Medicaid savings in 2001." (*Id.*) Had CMS followed its own guidelines and implemented a FUL for ipratropium bromide, the Medicaid program would have saved nearly $20 million in 2001 alone. (*Id.* at 7) CMS failed to implement a FUL for ipratropium bromide until August 24, 2003. (*Id.*)

123. The OIG also studied Medicare reimbursement for ipratropium bromide and found that had CMS reimbursed Medicare providers based on the FUL implemented in 2003 instead of the pre-2004 Medicare reimbursement guideline of 95% of AWP, the Medicare program and its beneficiaries would have saved $386 million in 2002 alone. (Tab 141, Abbott Ex. 122 at ii-iv, OIG, Jan 2004, *Update: Excessive Medicare Reimbursement for Ipratropium Bromide*, (OEI-03-03-00520) (Jan. 2004 OIG Report)) ("This report is part of a series of reports on ipratropium bromide that have consistently found that the published average wholesale prices, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers."))

XV. ROXANE PROVIDED AMPs DIRECTLY TO CMS

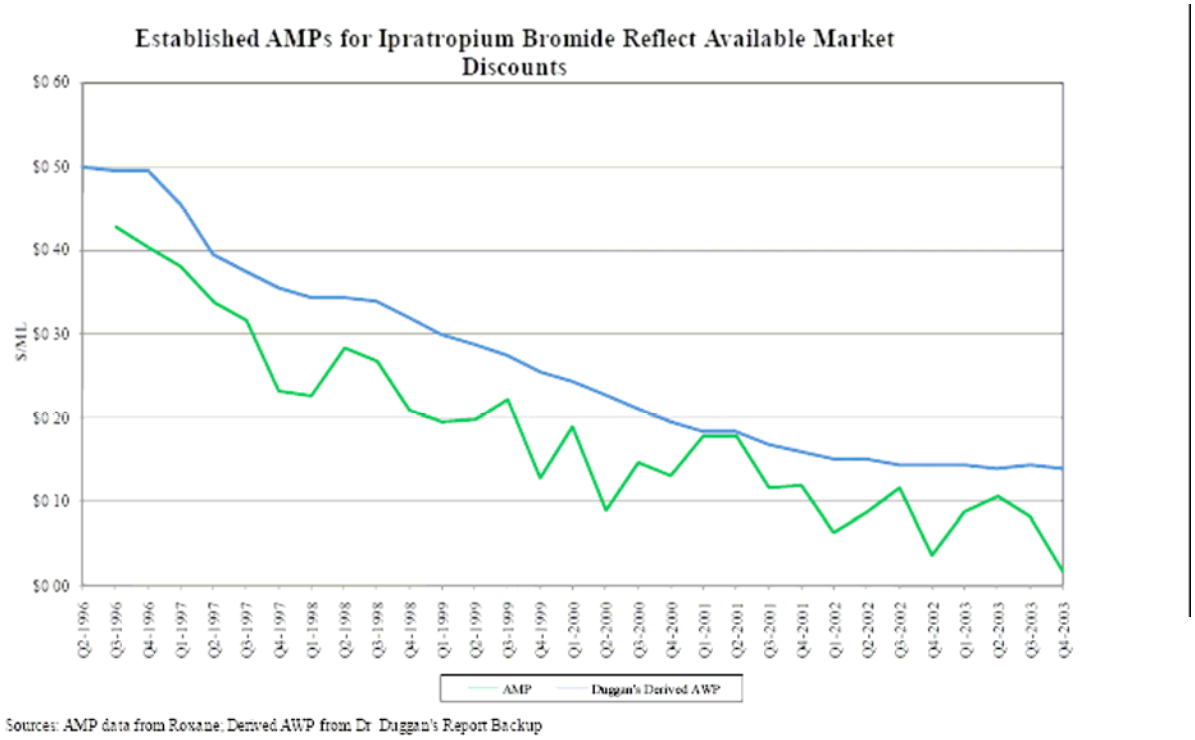
124. Congress created the Medicaid Drug Rebate Program ("Rebate Program") in the Omnibus Budget Reconciliation Act of 1990. Under the Rebate Program, for Roxane's drugs to be eligible for reimbursement under Medicaid, the manufacturer is required to enter into a national Medicaid Rebate Agreement with the Centers for Medicare and Medicaid Services ("CMS"). (42 U.S.C. § 1396r-8(a)(l); 56 Fed. Reg. 7049 (Feb. 21, 1991)).

125. Pursuant to the Medicaid Rebate Agreement Roxane signed with CMS, Roxane calculated the Average Manufacturer Price ("AMP") for all of its products – including all of the

drugs at issue in this case – during the entire time period relevant to this case, and reported that number to CMS on a quarterly or monthly basis. (Tab 14, 5-30-07 DeCapua Dep. 115-16; Tab 15, 7-15-08 DeCapua Dep. 16, 57-59; Tab 142, Scott Ex. 28, Sept. 2001 Medicaid Drug Rebate Operational Training Guide; Tab 143, 1991 Rebate Agreement entered into by Roxane Laboratories, Inc., dated 2-27-91 ("Roxane Rebate Agreement"))

126. Roxane calculated AMP according to CMS guidelines. (Tab 14, 5-30-07 DeCapua Dep. at 29, 137-42; Tab 15, 7-15-08 DeCapua Dep. at 61-65) Specifically, AMP is defined by statute as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." (42 U.S.C. § 1396r-8(k)(1)) AMPs "include cash discounts, free goods, volume discounts, and rebates." (Tab 144, H.R. No. 101-881, reprinted in 1990 U.S.C.C.A.N. 2017, 2060 [*quote from 2109] (1990); *see also* Tab 14, DeCapua 5-30-07 Ex. 82 at 2, "Boehringer Ingelheim Medicaid Reporting Requirements") AMP is therefore an average price, including discounts, to the retail class of trade under a defined set of circumstances. (Tab 15, 7-15-08 DeCapua Dep. at 39-40, 61-65, 78)

127. The AMP prices reported by Roxane to CMS throughout the relevant time period generally tracked the "Derived AWPs" calculated by Plaintiffs' expert, Dr. Mark Duggan. The below graph illustrates this relationship for ipratropium bromide, and the results are similar for the other Roxane drugs at issue. (Tab 188, D. Williams Aff. at ¶ 15)



128. CMS was not the only federal agency with access to Roxane's AMP information. The Department of Health & Human Services Office of Inspector General ("OIG") also had access to AMPs reported by drug manufacturers. (Tab 57, 2-6-08 Vito Dep. 1096-99, 1194-98) (Tab 52, 12-13-07 Tawes Dep. 879-80) In fact, the OIG was given direct access to Roxane's reported AMPs and could view such information without first requesting it through CMS. (Tab 57, 2-6-08 Vito Dep. 1197-98)

129. Several Federal agencies, including the OIG and Congressional Budget Office ("CBO"), used AMPs reported by manufacturers extensively in reports comparing AMP prices to AWPs, FULs, and other published prices. *See, e.g.*, Tab 91, Dey Ex. 173A at 20, Box 2, Jan. 1996 CBO Report, "How The Medicaid Rebate On Prescription Drugs Affects Pricing In The Pharmaceutical Industry," (1996 CBO Report)); Tab 146, Dey Ex. 009, OIG June 2005, OIG, Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices, OEI-03-05-00110, (June 2005 OIG Report)); Tab 147, Littlejohn Ex. 233, OIG June 2005,

Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices, OEI-05-05-00240, June 2005; Tab 148, OIG April 2006, Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices, OEI-03-04-00430 (April 2006 OIG Report.)

XVI. STATES ALSO GAIN INFORMATION FROM ROXANE'S AMPs

130. CMS used Roxane's AMP information to calculate and send to the states a "Unit Rebate Amount" (URA) for each covered drug. The states then used the URA to calculate federally-mandated rebates Roxane was required to pay by multiplying the URA by the number of units of the drug supplied to Medicaid beneficiaries. (42 U.S.C. § 1396r-8(b)(3)(A); Tab 14, 5-30-07 DeCapua Dep. 50; Tab 15, 7-15-08 DeCapua Dep. 57-59) For most generic drugs, the URA is equal to 11% of the product's AMP provided to CMS by Roxane. (42 U.S.C. § 1396r-8(c)(3); Tab 44, 10-2-08 L. Reed Dep. 1315-16; Tab 14, 5-30-07 DeCapua Dep. 161-62)

131. Because the formula for calculating the URA for most generic drugs is very simple — 11% of a drug's reported AMP — states could easily determine a drug's AMP from the URA provided to the State by CMS. (Tab 39, 7-11-07 Megathlin (Massachusetts) Dep. 139-41; Tab 28, 1-15-09 Gladden (Texas) Dep. 55-57) Indeed several States admitted to reverse calculating AMP from the URAs received from CMS. (Tab 31, 6-14-07 Jeffrey (Massachusetts) Dep. 114-15; Tab 28, 1-15-09 Gladden (Texas) Dep. 98-100).

132. State Medicaid programs understood the significance of AMPs and wanted AMP information so they could compare AMPs to prices used for reimbursement. (Tab 28, Gladden (Texas) Ex. 38 at 3 (State Medicaid Directors' Association Pharmacy Reform TAG meeting minutes reflecting discussion regarding the States' "need to know both AMP and best price for policy reasons (to establish a pharmacist reimbursement baseline)…"); Tab 28, 1-15-09 Gladden

(Texas) Dep. 47-48, 96-97; Tab 150, KS 00000042 (Kansas Medicaid compared AMPs provided by CMS to FULs and MACs used for drug reimbursement))

133. Though only restriction of the states' use of URA information is that states cannot publicly disclose the identity of a specific manufacturer or prices charged by that manufacturer. Under federal regulations State Medicaid programs were permitted to use URA and AMP information as a "baseline" for reimbursement and as a comparison for reimbursement benchmarks. (Tab 138, 42 U.S.C. § 1396r-8(b)(3)(D) ("(I)information disclosed by manufacturers or wholesalers … is confidential and shall not be disclosed by … a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler (or) prices charged for drugs by such manufacturer or wholesaler …."); Tab 143, Roxane Rebate Agreement § VII; Tab 28, 1-15-09 Gladden Dep. 60-61, 92-93; 96-97)

134. Indeed, some States have passed laws requiring manufacturers to provide AMPs directly to State Medicaid programs, including Texas (2002), Vermont (2008), New Mexico (2005), and Maine (2005). (*Id*. 94-96; VT. STAT. ANN. tit. 33, § 2010 (Vermont); N.M. STAT. § 27-2E-1 (New Mexico); ME. REV. STAT. ANN. tit. 22, § 2698-B (Maine))

XVII. THE GOVERNMENT'S NOVAPLUS CLAIMS

A. Roxane Named And Priced NovaPlus Label Ipratroprium Bromide Identically To Roxane Label Ipratropium Bromide And Considered Both Generic Drugs.

135. In June 1996, Roxane began manufacturing and marketing the first generic version of the chemical compound, ipratropium bromide, which is used to treat symptoms associated with chronic respiratory conditions. (Tab 62, 10-24-01 Waterer Dep. 38-39; Tab 65, 5-10-07 Waterer Dep. 292-94.) Roxane marketed and sold the drug under the name "Ipratropium Bromide Inhalation Solution 0.02%." (Tab 151, RLI-AWP 00212508-09 at RLI-AWP 00212508 (9-19-2000 Ltr. from J. Powers to S. Norvell).)

136. Both prior to 1996 and thereafter, the brand-name product for ipratropium bromide was sold and marketed under the proprietary trade name "Atrovent." (Tab 5, 12-12-08 C. Carr-Hall Dep. 244; Tab 152, Decl. C. King ¶ 18.)

137. In accordance with industry practice, Roxane set the AWP for its new ipratropium bromide generic product at approximately 10% below the AWP of Atrovent. (Tab 64, 11-28-05 Waterer Dep. 37; Tab 65, 5-9-07 Waterer Dep. 186-87; Tab 65, 5-11-07 Waterer Dep. 604.)

138. In 1997, Dey Laboratories launched a competing generic product, also named after the generic chemical compound, "Ipratroprium (Bromide Inhalation Solution 0.02%.)" (Tab 36, 03-17-08 Lockwood Dep. 646-48; Tab 5, Carr-Hall Dep. Ex. 40 at BOEH01050028, "Dey Recognize the Difference" (Dey Marketing Flier).) This product had a Dey label. (*Id*.)

139. From 2000 onward, numerous generic manufacturers entered the ipratropium bromide marketplace, including Alpharma, Zenith Goldline, and others. (Tab 185, Roxane Ex. 118 at AWP033-434–AWP033-435, AWP033-0372–AWP033-373 (AdminaStar Federal pricing arrays); Tab 53, 12-2-08 Tawes Dep. 978.) Like the Roxane and Dey products, all of these manufacturers named their generic products after the chemical compound name, "ipratropium bromide," and all carried the respective manufacturer or distributor label. (Tab 154, 2001 RedBook at 368.)

140. In 1998, Roxane and Dey bid on a private-label contract to sell generic ipratropium bromide through Novation LLC, a large group-purchasing organization (GPO) that targets the hospital class of trade. (Tab 155, RLI-AWP-00122465-470 at RLI-AWP 00122467, "Novation Agreement Launch Package, Confidential" (NovaPlus Ipratropium Agreement Launch Package); Tab 66, 12-12-08 C. Carr-Hall Dep. 236-237; Tab 5, 12-12-08 Waterer Dep. 116.)

141. In order to facilitate the sale of lower-priced products to its member hospitals, Novation created a private label program—the "Products Lowered Utilizing Standardization" or "NovaPlus" label—which consists of over 300 generic products, all of which carry the private-label designation of "NovaPlus" to identify the supplier for Novation's hospital members.

(Tab 156, htttp://www.novationco.com/suppliers/novaplus.asp; Tab 157, http://www.novationco.com/programs/enhanced_savings.asp.) As part of the NovaPlus program, Novation contracts with manufacturers of pharmaceuticals and medical equipment to supply products that will be sold exclusively to Novation GPO members at discounted prices under the "NovaPlus" label. (Tab 156, http://www.novationco.com/suppliers/novaplus.asp; Tab 157, http://www.novationco.com/programs/enhanced_savings.asp.)

142. In early 1999, Roxane was awarded the NovaPlus contract by Novation and began to manufacture generic ipratropium bromide for sale exclusively to Novation's hospital members under the NovaPlus label. (*Id.*; Tab 158, RLI-AWP-00122479–RLI-AWP-00122482 at RLI-AWP-00122479 (Novation, LLC Agreement Announcement).) Like Roxane's and Dey's products, the Novation product was named after the generic chemical name, "Ipratropium Bromide Inhalation Solution 0.02%," but carried the "NovaPlus" label, rather than a Roxane label. (Tab 151, RLI-AWP 00212508-09 (9-19-2000 Ltr. from J. Powers to S. Norvell); Tab 155, NovaPlus Ipratropium Agreement Launch Package at RLI-AWP 00122468; Tab 159, RLI-AWP-00008196 (April ' 99 New from Roxane).)

143. Shortly before the product's launch in June 1999, Roxane sent out letters announcing the private-label agreement. (*See, e.g,* Tab 158, Novation Agreement Announcement, RLI-AWP-00122479-82.) These letters identified the new product as

"Ipratropium Bromide Inhalation Solution 0.02% with a NOVAPLUS® label" and "Ipratropium Bromide Inhalation Solution 0.02% (NovaPlus)." (Tab 158, Novation Agreement Announcement at RLI-AWP-00122479-82; Tab 159, April '99 New from Roxane at RLI-AWP 00008196).

144. Roxane's letters also listed new Roxane NDCs for the product and the same AWPs for the NovaPlus labeled products that were used for Roxane's other generic ipratoprium bromide products. (Tab 158, Novation LLC Agreement Announcement at RLI-AWP-00122479-82; Tab 159, April '99 New from Roxane at RLI-AWP 00008196).

145. The AWPs for the Roxane and NovaPlus label ipratroprium bromide products were identical. The following chart shows the AWPs for each of these products, which remained the same throughout the pertinent time period

Package Size	Roxane ipratroprium bromide	NovaPlus ipratropium bromide
25	$44.06	$44.06
30	$52.87	$52.87
60	$105.74	$105.74

(Tab 158, Novation LLC Agreement Announcement at RLI-AWP-00122479-82.)

146. Roxane sold the NovaPlus label ipratropium bromide to Novation members at a contract price that was at or at times lower than the contract price for Roxane label ipratropium bromide. (Tab 151, 9-19-2000 Ltr. from J. Powers to S. Norvell at RLI-AWP 00212508).)

147. It was Roxane's understanding that NovaPlus was a generic pharmaceutical product. (Tab 66, 12-12-08 Waterer Dep. 105)

148. Novation also sent mailings to its members announcing it would "introduce Iptratropium Bromide into the NOVAPLUS™ line of products." (Tab 160, 4-6-99 S. Norvell Memo to Novation Authorized Distributors at RLI-AWP 00224752; Tab 161, 4-14-1999 S. Norvell Revised Memo to Novation Authorized Distributors at RLI-AWP 00122471-85.)

Another mailing announced the launch of "NOVAPLUS™ Ipratropium Bromide." (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package at RLI-AWP 00122465-70.)

149. From June 1999 until May 2004, the NovaPlus label ipratropium bromide was sold exclusively to Novation members under the private-label agreement. (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package at RLI-AWP 00122465-70; Tab 162, BOEH01522558, "The Multi-Source Gold Sheet, March 22, 2004" (March Gold Sheet); Tab 163, BOEH02953413, "The Multi-Source Gold Sheet, April 8, 2004" (April Gold Sheet); Tab 164, BOEH02953409, "The Multi-Source Gold Sheet, May 3, 2004" (May Gold Sheet).)

150. Roxane and Novation's Agreement was initially set to expire in January 2004. (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package, RLI-AWP 00122465-70). But due to lack of demand, the decision to discontinue NovaPlus ipratropium bromide was made in June 2003 and official notice was sent to Novation in July 2003. (Tab 165, BOEH04310697, 7-11-03 Ltr. from L. Paoletti to R. Day). The NovaPlus-label ipratropium bromide product was discontinued between March-May 2004. (Tab 162, March Gold Sheet at BOEH01522558; Tab 163, April Gold Sheet at BOEH02953413; Tab 164, May Gold Sheet at BOEH02953409.)

B. The Medicare Regulatory Framework For Hospital Reimbursements Under The Medicare Parts A and B.

151. Drugs dispensed to Medicare beneficiaries during inpatient hospital stays are not paid for separately but are reimbursed along with procedures as part of a bundled package through diagnosis-related groups under Medicare Part A. *See* 42 U.S.C. § 1395ww(a)(4).

152. Beginning on July 1, 2000, drugs dispensed to Medicare beneficiaries during outpatient hospital visits to Hospital Outpatient Departments (OPDs), including hospital pharmacies, are reimbursed under Medicare Part B's Outpatient Prospective Payment System

(OPPS). *See* 42 U.S.C. § 1395l(t)(2); 65 Fed. Reg. 18434, 18436 (April 7, 2000) Similar to Medicare Part A, Medicare Part B's OPPS typically reimburses drugs dispensed in OPDs on a "package" basis under an Ambulatory Payment Classification System, which is comprised of all items and services for that procedure, identified by their individual J-codes and/or other HCPCS codes—meaning that under the OPPS, Medicare Part B pays for all items and services related to a procedure with a lump sum—not for individual drugs based on claims made under J-codes. *See* 42 U.S.C. § 1395l(t)(2); 42 C.F.R. §§ 419.21, 419.31; addenda to 65 Fed. Reg. 18434 (April 7, 2000).

153. Because Novation's membership consists almost exclusively of hospitals, and given the structure of the Medicare regulatory scheme, it is unlikely that very many NovaPlus ipratropium bromide prescriptions were reimbursed under the Medicare program. (Tab 45, 5-18-09 Scott Morton Dep. 341-44, 346-48.)

154. According to plaintiffs' expert, Dr. Mark G. Duggan, "Roxane's NovaPlus products, at least for Medicaid, account for a miniscule share of all Medicaid prescriptions for ipratropium bromide." (Tab 18, 3-5-09 Duggan Dep. 187.) Dr. Duggan uncovered only 48 NovaPlus ipratropium bromide prescriptions paid for by the Medicaid program throughout the entire United States during the six-year period that NovaPlus ipratropium bromide was sold. (*Id*. 186-188; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 127.)

155. Dr. Duggan estimated, based on an extrapolation from the number of Medicaid prescriptions that perhaps only 150 NovaPlus ipratropium bromide prescriptions were reimbursed out of the 12.8 million ipratropium bromide prescriptions paid for under Medicare Part B over the same span. (Tab 18, 3-5-09 Duggan Dep. 188; Tab 20, 5-18-09 Duggan Dep. 156-57; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 127.)

C. The DMERCs' Inconsistent And Private Procedures For Constructing Pricing Arrays And Establishing Payment Rates.

156. HCFA and later CMS delegated the task of setting the maximum reimbursement rate for Medicare Part B drugs dispensed via durable medical equipment (DME) to private contractors called durable medical equipment regional carriers (DMERCs). *See* 42 U.S.C. § 1395m(a)(12); 42 C.F.R. § 421.210. The country is divided into four DME regions and each DMERC, following HCFA/CMS guidelines, sets the maximum Medicare rate for DME drugs within its region. *See* 42 U.S.C. § 1395m(a)(12); 42 C.F.R. § 421.210; http://www.ezdme.com/aboutez/dmerc_regions.htm.

157. During the pertinent time period there were four DMERCs that processed ipratropium bromide claims under Medicare Part B. (Tab 50, 2-29-08 Stone Dep. 422-23.) The four DMERCs were generally known as DMERC-A, AdminaStar Federal, Palmetto, and Cigna. (Tab 18, 3-5-09 Duggan Dep. 130-31.)

158. Throughout the relevant period, in order to maintain oversight and facilitate compliance with the applicable regulations, HCFA and CMS would issue program memoranda to the carriers, including the DMERCs, which were "instruction[s] to our carriers who administer the Medicare program." (Tab 40, Niemann Dep. 365; *see also* Tab 51, 4-25-07 Tawes Dep. 435 ("A program memorandum is a memo sent to intermediaries or carriers by CMS headquarters").)

159. By regulation, when pricing drugs for reimbursement purposes under Medicare Part B, the DMERCs were required to utilize the lesser of the "median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517 (emphasis added); *see also* Tabs 167-168, Roxane Exs. 41 and 42, AWQ025-0722 and AWQ025-0880 (Medicare Professional Reimbursement Desk Procedure - Drug Pricing Procedure).

160. Each of the DMERCs independently set maximum reimbursement rates for its region by consulting the pricing compendia, converting the published AWPs of the drugs selected from the compendia into unitized prices by dividing the published AWPs by the quantity or strength of the packaged drug, compiling those prices into worksheets called pricing arrays, and then calculating the median price of these arrays. (Tab 22, 8-26-08 Eiler Dep. 47-49, 116; Tab 30, Helton Dep. 22-23; Tab 167, Roxane Ex. 41 at AWQ025-0722– AWQ025-0725 (Drug Pricing Procedure); Tab 169, Roxane Ex. 100 at AWP034-0462–AWP034-0466 (Drug Pricing Procedure); Tab 170, Abbott Ex. 524 at HHD008-0282– HHD008-0287 (Medicare Professional Reimbursement Desk Procedure).)

161. When the median AWP of the generic sources of a drug and the lowest AWP for a brand source were equivalent, the DMERCs used one of the prices as the maximum allowable rate, but could not tell which price actually set the reimbursement rate. (Tab 30, Helton Dep. 230-31; Tab 49, 2-28-08 Stone Dep. 194.)

162. The DMERCs' arrays and classification of drugs were not publicly available. (Tab 22, 8-26-08 Eiler Dep. 157-58.)

163. Although HCFA directives to the DMERCs allowed for consideration of a wide variety of published sources, such Red Book, Blue Book, or Medispan, in practice the DMERCs limited their review exclusively to the Red Book compendium. (*See, e.g.*, Tab 171, Abbott 1015, HHC021-0030, December 1998 HCFA Transmittal; Tab 22, 8-26-08 Eiler Dep. 27-28, 47-48, 116-19, Tab24, 9-23-08 Eiler Dep. 481-82; Tab 30, Helton Dep. 22-23, 36, 37; Tab 49, 2-28-08 Stone Dep. 34-35, 65-66, 87-88; Tab 183, Decl. of C. King ¶ 7; Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project).)

164. During the relevant period, the four DMERCs updated their pricing arrays at different times, and also selected prices from different Red Book sources that were not always consistent. (Tab 22, 8-26-08 Eiler Dep. 125-26, 135-36; Tab 30, Helton Dep. 108, 224-26, 237; Tab 50, 2-29-08 Stone Dep. 284-86.) For example, sometimes one DMERC would receive a monthly update earlier than the other DMERCs, so they would use the update while the other DMERCs would use an outdated version. (Tab 22, 8-26-08 Eiler Dep. 135-36; Tab 30, Helton Dep. 158-59.)

165. The inconsistent use of different versions of Red Book sometimes resulted in drugs being omitted from a DMERC's array in one quarter and then reappearing in a later quarter. (Tab 23, 8-27-08 Eiler Dep. 280-86, 295-96.)

166. The DMERCs varied widely in the sources of Red Book that they relied upon, with some DMERCs using the annual update, others consulting the monthly updates or quarterly electronic CDs, and others using both at times. (Tab 22, 8-26-08 Eiler Dep. 47-48, 125-26, 133-34; Tab 24, 9-23-08 Eiler Dep. 481-82; Tab 30, Helton Dep. 44-45, 224-26; Tab 49, 2-29-08 Stone Dep. 113; Tab 50, 2-29-08 Stone Dep. 284-85; Tab 183, Decl. of C. King ¶¶ 7, 9; Tab 168, Roxane Ex. 42 at AWQ025-0876–AWQ025-0887 (12-1-99 Ltr. from R. Stone to C. Carpenter).)

167. Each DMERC separately decided how to construct the arrays by reviewing the descriptions in the compendia, and by also consulting other external resources such as reference guides and medical directors that each DMERC had on staff and by exercising their judgment. (Tab 22, 8-26-08 Eiler Dep. 27, 48-49, 58-59, 119-20, 149, Tab 24, 9-23-08 Eiler Dep. 487-88; Tab 30, Helton Dep. 89, 160-61; Tab 49, 2-28-08 Stone Dep. 77-78, 86, Tab 50, 2-29-08 Stone

Dep. 275-76; Tab 53, 8-27-08 Eiler Dep. Roxane Ex. 41 at AWQ025-0722–AWQ025-0725 (Drug Pricing Procedure).)

168. At times the narrative description of a drug in Red Book was not clear enough for the DMERCs to determine whether to include the drug in their pricing arrays, which meant that sometimes the DMERCs had to use their own judgment in making that determination. (Tab 24, 9-23-08 Eiler Dep. 487.)

169. As such, DMERCs did not consistently include all forms of a drug in their arrays. (Tab 22, 8-26-08 Eiler Dep. 48, 147-148, Tab 24, 9-23-08 Eiler Dep. 487-88; Tab 30, Helton Dep. 150-51; Tab 50, 2-29-08 Stone Dep. 298-299)

170. The AdminaStar Federal DMERC acknowledged this divergence, stating that other DMERCs "did things a little different than we did." (Tab 22, 8-26-08 Eiler Dep. 128.)

171. The DMERCs noted in correspondence with HCFA that they had issues "determining the correct forms of the drugs to pickup from REDBOOK," and asked HCFA to make program memoranda "more specific in what items should be excluded and/or included in the calculation" in order to "help eliminate the wide interpretations by different carriers." (Tab 172, Roxane Ex. 51 at AWQ029-00327 (Uniform Drug Pricing Project); *see also* Tab 30, Helton Dep. 160-61.)

172. Although the DMERCs at times contacted manufacturers to verify prices for durable medical equipment, they never contacted the manufacturers to verify the pricing for drugs listed in Red Book. (Tab 22, 8-26-08 Eiler Dep. 73.)

173. Because of the historic variance in payment rates across DMERCs for the same drugs, beginning in approximately 1997, continuing with the "Uniform Drug Pricing Project" in 1999, and again in 2001, the DMERCs consulted and shared information with each other to

reduce inconsistencies—usually without any participation by HCFA/CMS. (Tab 22, 8-26-08 Eiler Dep. 127-28, 135-36, 153-54, 166-67, 171-72; Tab 30, Helton Dep. 99-100, 144-46, 169-71, 277-78; Tab 50, 2-29-08 Stone Dep. 282-83; Tab 183, Decl. of C. King ¶ 17; Tab 168, Roxane Ex. 42 at AWQ025-0876–AWQ025-0887 (12-1-99 Ltr. from R. Stone to C. Carpenter); Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project); Tab 173, Roxane Ex. 52 at AWQ029-000104– AWQ029-000105 (5-15-01 E-mail from R. Stone to C. King, C. Eiler, C. Helton, B. Douglas, and V. Brantley); Tab 169, Roxane Ex. 100 at AWP034-0462–AWP034-0466 (Drug Pricing Procedure); Tab 174, Roxane Ex. 102 at AWP039-1420 (7-6-99 E-mail from C. King to C. Eiler).) The DMERCs did not, however, coordinate their construction of arrays or ensure that all four DMERCs were using the same published prices or classifying drugs in an identical way. (Tab 22, 8-26-08 Eiler Dep. 153-54; Tab 30, Helton Dep. 108-09, 144-46; Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project; Tab 174, Roxane Ex. 102 at AWP039-1420 (7-6-99 E-mail from C. King to C. Eiler).)

D. HCFA's Regulations And Directives Distinguished Generics From Brands Based On Whether The Drug Used Its Generic Chemical Name.

174. On November 2, 1998, HCFA implemented a final rule that revised its payment methodology for generics under Medicare Part B to include consideration of AWPs for brand drugs. *See* 63 Fed. Reg. 58813, 58849 (1998) (Tab 112, Abbott Ex. 209). HCFA adopted a payment formula for generic drugs that required Medicare carriers, including the DMERCs, to compare "the lower of the median price of the generic AWPs" with "the lowest brand name AWP," and then pay the lower amount. *Id.*; *see also* 42 CFR § 405.517 (1998).

175. In response to a comment generated during the rulemaking process, HCFA provided the following definition of what it considered to be a "brand" for purposes of Medicare Part B payments:

> Our definition of "brand" is any product that is marketed under a name other than the generic chemical of the drug. If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand . . . . A "brand" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological.

(Tab 112, Abbott Ex. 209).

176. HCFA also included a near-identical definition of "brand" as in the regulation in a program memorandum issued to carriers following the regulation: "A 'brand name' product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological." ((Tab 171, Abbott Ex. 1015 at HHC201-0030 (HCFA Program Memorandum, Transmittal No. AB-98-76; Tab 175, Abbott Ex. 529 at AWQ025-1349 (HCFA Program Memorandum, Transmittal No. AB-98-76).)

177. The Medicare Supplier Bulletin that preceded the November 1998 regulation also illustrated this distinction by including a table listing generic names in one column and the corresponding trade/brand names in the next. (Tab 176, Eiler Ex. 6 at AWQ058-0950, ("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0223, ("Cigna DMERC: Nebulizer Medications".) One of the entries explicitly listed "ipratropium bromide" as the "generic" and "Atrovent" as the corresponding "trade/brand" name. (Tab 176, Eiler Ex. 6 at AWQ058-0950, ("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0223, "Cigna DMERC: Nebulizer Medications".) In every instance, the trade/brand example was comprised solely of a proprietary trade name, and did not include the underlying chemical compound in the name of the drug. (Tab 176, Eiler Ex. 6 at

AWQ058-0950, ("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0224, ("Cigna DMERC: Nebulizer Medications".)

178. In December 1998, HCFA issued a Program Memorandum that directed the Medicare DMERCs to implement the November 1998 regulatory changes. (Tab 171, Abbott Ex. 1015 at HHC201-0030 (HCFA Program Memorandum, Transmittal No. AB-98-76); Tab 175, Abbott Ex. 529 at AWQ025-1349 (HCFA Program Memorandum, Transmittal No. AB-98-76).) HCFA directed the carriers to obtain published AWPs from "sources such as the Red Book, Blue Book, or Medispan." (*Id.*)

E. The DMERCs' Idiosyncratic And Private Classification Criteria Ignored And Were Inconsistent With HCFA's Regulatory Definitions And Directives.

179. Throughout the relevant period the DMERCs constructed separate arrays for generic and brand versions of ipratropium bromide to determine whether the median of the generic AWPs was lower than the lowest brand AWP. (Tab 24, 9-23-08 Eiler Dep. 547; Tab 18, 3-5-09 Duggan Dep. 146)

180. In determining whether a drug was a generic versus a brand, the DMERCs' Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure ("Drug Pricing Procedure") did not use the regulatory definition that a "brand" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological." (Tab 22, 8-26-08 Eiler Dep. 145-46, Tab 24, 9-23-08 Eiler Dep. 485, 547-49 ("Q: Now I want to suggest to you, Ms. Eiler that Novaplus actually has always been a generic product, not a brand product. And that if one – I want you to assume that if one had done additional research, the generic status of that drug might have been discovered . . ."), 558-603 ("Q: Okay. I'd like you to assume today that in fact they're [Novaplus NDCs] generic drugs, and that if you have done some additional research, besides just looking at the RedBook, you

might have determined that they were in fact generics."); Tab 30, Helton Dep. 253-54; Tab 168, Roxane Ex. 42 (12-1-99 Ltr from R Stone to C. Carpenter), Tab 169, Roxane 100 (Drug pricing Procedure).) Instead, the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure directed the DMERCs to use the following methodology to determine whether a drug was a brand drug:

> To determine if a drug is generic or brand, look at the bold face upper case name of the drug [in the Drug Topics Red Book publication]. If there is another name for the drug immediately below it in lower case letters (the generic name), the entries following are generally brands. If there is no lower case drug name immediately below the bold face upper case name, the bold face upper case name is the generic name and all the entries below are generics. In either case, if an entry below the drug name refers to another page, that entry would be for a brand name. If there is a question as to whether a drug is brand or generic, consult the PDR Generics, telephone the drug company or **Red Book** (1-800-222-3045).

(Tab 168, Roxane Ex. 42 at AWQ025-0881-82, (12-1-99 Letter from R. Stone to C. Carpenter – Drug Pricing Procedure) (emphasis in original); (*see also* Tab 22, 8-26-08 Eiler Dep. 145-46; Tab 24, 9-23-08 Eiler Dep. 485, 547-49; Tab 169, Roxane 100 (Drug Pricing Procedure).

181. The DMERCs sometimes determined whether a drug was a brand by whether it had the word "See" in the Red Book, indicating a cross reference. (Tab 30, Helton Dep. 253-54)

182. The DMERCs also sometimes made the brand/generic classification without consulting the printed Red Book. (Tab 24, 9-23-08 Eiler Dep. 600-03.) On those occasions, DMERCs would review certain files on a Red Book CD database that did not have the same capitalization convention as the printed volumes but instead listed the brand drugs in separate data files. (*Id.*; Tab 50, 2-29-08 Stone Dep. 305-310.)

183. Once a DMERC made the initial determination of whether a drug was a generic or a brand, the DMERC would carry that same classification through in subsequent quarters unless "some notation in the RedBook . . . indicated it had changed from branded to generic or vice versa." (Tab 24, 9-23-08 Eiler Dep. 603.)

184. The Annual Red Book did not begin listing the NDCs for the NovaPlus label ipratropium bromide inhalation solution until 2001. (*Compare* Tab 154, 2001 RedBook at 368 *with* Tab 178, 2000 Red Book at 369.)

185. In the 2001 Annual Red Book, under the bold-faced, upper-case **IPRATROPIUM BROMIDE** heading in the left-hand column, the Red Book listed all ipratropium products by manufacturer. (Tab 154, 2001 Red Book at 368.) For example, under the **IPRATROPIUM BROMIDE** heading it listed generic ipratropium bromide products by **(Alpharma USPD), (Dey), (Roxane)** and **(Zenith Goldline)**. (*Id.*)

186. The 2001 Annual Red Book listed the three NovaPlus label ipratropium bromide NDCs (0054-8404-11, 0054-8404-13, 0054-8404-21) directly underneath to the Roxane label ipratropium bromide NDCs (0054-8402-11, 0054-8402-13, 0054-8402-21). (*Id*.) All six NDCs were listed under the "**(Roxane)"** manufacturer designation. (*Id*.)

187. The 2001 Annual Redbook listed identical AWPs for the three Roxane label NDCs and the corresponding NovaPlus label NDCs of the same package sizes. (*Id.*) For example, the Roxane-label 2500 ml 25s unit dose vial (NDC 00054-8402-11) listed an AWP of 44.06; the NovaPlus-label 2500 ml 25s unit dose vial (NDC 00054-8404-11) listed the same AWP of 44.06. (*Id.*)

188. The 2001 Annual Red Book descriptions for the three NovaPlus label NDCs were identical to the corresponding package sizes for the three Roxane label NDCs. For example, all six NDCs contained the description "SOL, IH (S.D.V. […] PROTECTAPAK 0.02%." (*Id.*)

189. The 2001 Annual Red Book listings for the NovaPlus-label NDCs did not contain the word "NovaPlus" anywhere under any of the **IPRATROPIUM BROMIDE** listings or **(Roxane)** NDC sub-listings. (*Id.*)

190. The 2001 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "See" next to the NovaPlus label or Roxane label NDCs. (*Id.*)

191. The 2001 Annual Red Book contained a listing under the **IPRATROPIUM BROMIDE** heading that read as follows: **(Boehr Ingelheim)** *See ATROVENT.* (*Id.*)

192. The 2001 Annual Red Book listing for the Roxane label or NovaPlus label ipratropium bromide did not contain the word "ipratropium bromide" in either bold face or capitals under the **(Roxane)** listing. (*Id.*)

193. The 2001 Annual Red Book listing did not contain a separate entry for "IPRATROPIUM BROMIDE NOVAPLUS." (*Id.*)

194. Other than different NDC numbers, the NovaPlus label NDC listings in the 2001 Annual Red Book were identical to the corresponding package sizes of the Roxane-label NDCs. (*Id.*)

195. The 2001 Annual Red Book listings for the NovaPlus NDCs identified them as generic drugs under the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr. from R. Stone to C. Carpenter, Drug Pricing Procedure). There was a "bold face upper case name," (*i.e.*, **IPRATROPIUM BROMIDE**) in the 2001 Annual Red Book listing, but there was not "another name for the drug immediately below it in lower case name letters (the generic name)," and thus the entry did not indicate a brand. (Tab 154, 2001 Red Book at 368; *supra* ¶¶ 46, 51-60.) Because "there is no lower case drug name immediately below" **IPRATROPIUM BROMIDE,** ipratropium bromide "is the generic name and all the entries below are generics." (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr from R Stone to C Carpenter.)

196. The 2001 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Adminastar DMERC for distinguishing brand from generic drugs. (Tab 24, 9-23-00 Eiler Dep. 547-49).

197. The 2001 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Cigna DMERC for distinguishing brand from generic drugs. (Tab 30, Helton Dep. 253-54). Specifically, the word "see" was not next to any of the NovaPlus-NDCs. (Tab 154, 2001 Red Book at 368). According to the Cigna DMERC's criteria for identifying brand drugs, the 2001 Annual Red Book listing for "ATROVENT" identified that product as a brand product for ipratropium bromide because it had the word "See" and a cross-reference next to it. (Tab 30, Helton Dep. 253-54).

198. In the 2002 Annual Red Book, under the bold-faced, upper-case **IPRATROPIUM BROMIDE** heading in the left-hand column, the Red Book listed all ipratropium products by manufacturer. (Tab 180, 2002 Red Book at 389) For example, under the **IPRATROPIUM BROMIDE** heading it listed generic ipratropium bromide products by **(Alpharma USPD), (Dey), (Roxane)** and **(Zenith Goldline)**. (*Id.*)

199. The 2002 Annual Red Book listed the three NovaPlus-label ipratropium bromide NDCs (0054-8404-11, 0054-8404-13, 0054-8404-21) directly underneath to the Roxane label ipratropium bromide NDCs (0054-8402-11, 0054-8402-13, 0054-8402-21). (*Id.*) All six NDCs were listed under the "**(Roxane)"** manufacturer designation. (*Id.*)

200. The 2002 Annual Red Book listed identical AWPs for the three Roxane-label NDCs and the corresponding NovaPlus-label NDCs of the same package sizes. (*Id.*) For example, the Roxane-label 2500 ml 25s unit dose vial (NDC 00054-8402-11) listed an AWP of

44.06; the NovaPlus-label 2500 ml 25s unit dose vial (NDC 00054-8404-11) listed the same AWP of 44.06. (*Id.*)

201. The 2002 Annual Red Book descriptions for the three NovaPlus label NDCs were identical to the corresponding package sizes for the three Roxane-label NDCs. For example, all six NDCs contained the description "SOL, IH (S.D.V. […] PROTECTAPAK 0.02%." (*Id.*)

202. The 2002 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "NovaPlus" anywhere under any of the **IPRATROPIUM BROMIDE** listings or **(Roxane)** NDC sub-listings. (*Id.*)

203. The 2002 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "See" next to the NovaPlus label or Roxane label NDCs. (*Id.*)

204. The 2002 Annual Red Book contained two listings under the **IPRATROPIUM BROMIDE** heading that read as follows: **(Boehr Ingelheim Pharm)** *See ATROVENT*. (*Id.*)

205. The 2002 Annual Red Book listing for the Roxane label or NovaPlus label ipratropium bromide did not contain the word "ipratropium bromide" in either bold face or capitals under the **(Roxane)** listing. (*Id.*)

206. The 2002 Annual Red Book listing did not contain a separate entry for "IPRATROPIUM BROMIDE NOVAPLUS." (*Id.*)

207. Other than different NDC numbers, the NovaPlus label NDC listings in the 2002 Annual Red Book were identical to the corresponding package sizes of the Roxane-label NDCs. (*Id.*)

208. The 2002 Annual Red Book listings for the NovaPlus NDCs identified them as generic drugs under the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, (Medicare Professional

Reimbursement Desk Procedure, Drug Pricing Procedure)). There was a "bold face upper case name," (*i.e.*, **IPRATROPIUM BROMIDE**) in the 2002 Annual Red Book listing, but there was not "another name for the drug immediately below it in lower case name letters (the generic name)," and thus the entry did not indicate a brand. (Tab 180, 2002 Red Book at 389; *supra* ¶¶ 46, 64-73.) Because "there is no lower case drug name immediately below" **IPRATROPIUM BROMIDE,** ipratropium bromide "is the generic name and all the entries below are generics." (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr. from R. Stone to C. Carpenter - Drug Pricing Procedure AWQ025-0876-79)).

209. The 2002 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Adminastar DMERC for distinguishing brand from generic drugs. (Tab 24, 9-23-08 Eiler Dep. 547-49).

210. The 2002 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Cigna DMERC for distinguishing brand from generic drugs. (Tab 30, Helton Dep. 253-54). Specifically, the word "see" was not next to any of the NovaPlus-NDCs. (Tab 180, 2002 Red Book at 389). According to the Cigna DMERC's criteria for identifying brand drugs, the 2002 Annual Red Book listing for "ATROVENT" identified that product as a brand product for ipratropium bromide because it had the word "See" next to it. (Tab 30, Helton Dep. 253-54).

211. Each time the DMERCs utilized the quarterly Red Book electronic CD databases by uploading a new electronic CD, the data provided on the previous electronic CD was deleted. (Tab 23, 8-27-08 Eiler Dep. 295.) The DMERCs could not keep a record of the data from the previous electronic CD other than by printing a hard copy. (*Id.*)

212. The few hard copy printouts produced by the DMERCS list *all* drugs—brand and generic—in all-capital letters. (Tab 24, 09-23-08 Eiler Dep. 600-03; Tab 179, AWP039-3207 (July 2000 Red Book for Windows printout); Tab 180, AWP038-0705 (April 2002 Red Book for Windows printout); Tab 189, AWP039-2444 (April 2000 Red Book for Windows printout).)

213. Although the internal procedures required the DMERCs to consult manufacturers, the Physicians Desk Reference book, or the Red Book itself if questions arose about the classification of a drug, there is no evidence that any DMERC did so with respect to classifying iptratropium bromide products. (Tab 22, 8-26-08 Eiler Dep. 119-20.)

214. The DMERCs did no additional research besides looking at RedBook to determine whether a drug was a generic or a brand. (Tab 24, 9-23-08 Eiler Dep. 559.) The DMERCs did not verify their classifications using First DataBank, Medispan, or any other compendia besides RedBook. (*Id*.)

215. First DataBank is a widely-used pricing compendium relied on by commercial and government third-party payors, including many State Medicaid programs, as well as others in the pharmaceutical industry to determine the generic status of NDCs. (Tab 182, Aff. of F. Scott Morton ¶ 7.)

216. In order to assist these entities in determining whether a drug is a generic or brand, First DataBank publishes a database containing several different "classification indicators." (Tab 182, Aff. of F. Scott Morton ¶ 3.)

217. Among others, these indicators include the "generic name drug indicator" and the "generic price indicator." (Tab 182, Aff. of F. Scott Morton ¶ 3.)

218. During the relevant time period, all of First DataBank's classification indicators were ***identical*** for Roxane-label and NovaPlus label ipratropium bromide. (Tab 182, Aff. of F. Scott Morton ¶ 6.)

219. For example, under "generic name indicator," First DataBank listed ***both*** the Roxane-label and NovaPlus-label ipratropium bromide as "Generically named AND multiple source." (Tab 182, Aff. of F. Scott Morton ¶¶ 5-6.)

220. Similarly, under "generic price indicator," First DataBank listed ***both*** the Roxane-label and NovaPlus-label ipratropium bromide as "Priced as a lower cost alternative." (Tab 182, Aff. of F. Scott Morton ¶¶ 5-6.)

F. Some Of The DMERCs Inconsistently Classified The Roxane And NovaPlus-Label Ipratropium Bromide Products As *Both* Brands And Generics, At Differing Times.

221. The four DMERCs varied considerably in their classifications of the NovaPlus and Roxane label ipratropium bromide products. (Tab 18, 3-5-09 Duggan Dep. 146). Of the four DMERCs, only DMERC-A consistently placed the NovaPlus and Roxane labeled products in its generic arrays throughout the pertinent time period. (Tab 183, Ex. A to Decl. of C. King at AWQ071-0043, AWQ071-0047, AWQ071-0052, AWQ071-0059, AWQ071-0063, AWQ071-0066, AWQ071-0070, AWQ071-0073, AWQ071-0077 (DMERC-A arrays).) The remaining three DMERCs classified either the NovaPlus label product or the Roxane label as a brand, and, in some instances, alternated the classification of the *same* product across time periods. (*See, e.g.*, Tab 24, 9-23-08 Eiler Dep. 549, 552-554; Tab 184, Eiler U.S. Ex. 11 (AdminaStar Federal Arrays) at AWP038-0704-05; Tab 185, Roxane 118 at AWP033-1352.)

222. The Palmetto DMERC placed the NovaPlus product in its generic arrays from April to July 2003, even though it had previously classified the product as a brand in prior arrays. (Tab 186, Roxane Ex. 46 at AWQ022-0074-AWQ-022-077.) Beginning in July 2003, Palmetto

re-classified the NovaPlus product as a brand and placed it back into its brand array. (Tab 186, Roxane Ex. 46 at AWQ022-0078- AWQ -022-081.)

223. The AdminaStar Federal DMERC classified the ***Roxane label*** ipratropium bromide as a brand for over one year, from July 2002 to October 2003, even though AdminaStar had previously classified it as a generic for the prior six years. (Tab 24, 9-23-08 Eiler Dep. 552-54; Roxane 118 at AWP033-1352, AWP033-1243, AWP033-1810, AWP033-1653-54, AWP033-2124, AWP033-1988; Tab 184, U.S. Eiler Ex. 11 (AdminaStar Federal arrays).)

224. Both the Cigna and AdminaStar DMERCs classified the NovaPlus label product as brand in all of the pricing arrays that listed the drug. (Tab 187, Roxane 58 (Cigna arrays); Tab 185, Roxane 118 at AWP033-0434-35, AWP033-0372-73, AWP033-0268-69, AWP033-1128-29, AWP033-0987-88, AWP033-0862, AWP034-1742, AWP033-0737-38, AWP033-0550-51, AWP033-1474, AWP033-1352, AWP033-1243, AWP033-1810, AWP033-1653-54, AWP033-2124, AWP033-1988 (AdminaStar Federal arrays).)

G. The Government's Damages Expert Includes Damages Based On The DMERCs' Classification Of NovaPlus As A Brand.

225. The Government's damages expert, Dr. Duggan attempted to determine the Government's damages by calculating the "difference" between (1) what the federal government reimbursed for Roxane's NDCs under Medicare and Medicaid from 1996 to 2008 and (2) what the federal government would have reimbursed during the same period if instead Dr. Duggan's average sales prices (derived from Roxane's indirect transactional data) had been used to determine the "actual" AWPs for Roxane's drugs. (Tab 18, 3-5-09 Duggan Dep. 61-64; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 1.)

226. Dr. Duggan's primary methodology consisted of replacing the published AWPs for Roxane's NDCs with his derived AWPs. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan

Report at 11.) He then placed the derived AWPs into electronic pricing arrays prepared based on the original DMERC arrays. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 98-99.)

227. In calculating what the federal government would have reimbursed under Medicare for ipratropium bromide, Duggan used the DMERCs' arrays without studying or attempting to check the DMERCs' prices against the compendia, correcting for inconsistencies, or scrutinizing the DMERCs' process for creating the pricing arrays. (Tab 18, 3-5-09 Duggan Dep. 132-34, 146-49, 152, 166.)

228. Dr. Duggan presented four independent damages models. (Tab 18, 3-5-09 Duggan Dep. 61-64.) One model calculated damages based on replacing prices for only the Roxane label ipratropium bromide and excluding the NovaPlus label ipratropium bromide products. (referred hereinafter as the "No-NovaPlus model") (Tab 18, 3-5-09 Duggan Dep. 61-64; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 3B.). A second model replaced prices for both the Roxane label and NovaPlus label ipratropium bromide NDCs. (hereinafter the "NovaPlus model") (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 3A; Tab 18, 3-5-09 Duggan Dep. 61-64.) The last two models calculated damages based on changing prices for Dey ipratropium bromide products in addition to the Roxane drugs. (Tab 18, 3-5-09 Duggan Dep. 61-64.)[1]

229. In the No-NovaPlus model, Dr. Duggan replaced Roxane's AWPs in the arrays with a "revised AWP" to determine whether Medicare spending would be affected. (Tab 18, 3-5-09 Duggan Dep. 140-41; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 98-99.) Dr.

[1] The two damages models that improperly incorporate Dey's independent published AWPs in calculating Roxane's damages are not the subject of this motion, except to the extent that one model incorporates the DMERCs' misclassification of NovaPlus as a brand.

Duggan calculated damages whenever replacing Roxane's prices affected the median of the generic array. (Tab 18, 3-5-09 Duggan Dep. 140-41.)

230. Dr. Duggan evaluated the electronic pricing array and lined up the prices. (Tab 18, 3-5-09 Duggan Dep. 131-32.) If there was an odd number of prices, he determined the median by disregarding the highest and lowest prices and taking the middle price. (Tab 18, 3-5-09 Duggan Dep. 131-32.) If there was an even number of prices, Dr. Duggan disregarded the highest and lowest prices and averaged the middle two prices. (Tab 18, 3-5-09 Duggan Dep. 131-32.)

231. Under the No-NovaPlus model, substituting Roxane's revised AWPs has no effect on the median later on in the relevant period for most of the DMERCs. (Tab 20, 5-18-09 Duggan, Dep. 184.)

232. For example, in the No-NovaPlus model, Dr. Duggan explained that the Palmetto DMERC's allowed amount was unaffected after the third quarter of 2001 when replacing Roxane's published AWPs with his derived AWPs. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 104; Tab 188, D. Williams Aff. at ¶ 11.)

233. Similarly, under Dr. Duggan's analysis, replacing Roxane's AWP with a revised AWP did not affect the median of the DMERC-A arrays after the third quarter of 2001. (Tab 188, D. Williams Aff. at ¶ 11.)

234. Under Dr. Duggan's analysis, replacing Roxane's AWP with a revised AWP also did not affect the median of the Cigna arrays after the third quarter of 2001 (*Id.*)

235. And under Dr. Duggan's analysis, replacing Roxane's AWP with a revised AWP did not affect the median of the AdminaStar arrays after the second quarter of 2000. (*Id.* at 10.)

236. Under the No-NovaPlus model, Duggan attempted to correct or reconcile some of the DMERCs errors based on "what [he] considered to be most appropriate at the time." (Tab 18, 3-5-09 Duggan Dep. 137-38.) For example, Duggan decided to correct AdminaStar's erroneous inclusion of the Roxane-label ipratropium bromide in the branded portion of the array. (Tab 18, 3-5-09 Duggan Dep. 138-41, 144-45.)

237. Under the NovaPlus model, Duggan replaced prices for both the Roxane label and NovaPlus-label AWPs. (Tab 18, 3-5-09 Duggan Dep. 62-63.) Dr. Duggan then calculated damages whenever replacing Roxane's prices would have affected the median of the generic array or the lowest brand price because, in his view, movement in either one would affect the allowed amount. (Tab 18, 3-5-09 Duggan Dep. 140-41.)

238. With respect to the NovaPlus label ipratropium bromide, Duggan did not attempt to determine whether the DMERCs' classification of the drug was appropriate and instead "accepted what [the DMERCs] did," relying on each DMERCs' separate determination of whether the drug was a brand or generic without correcting for any errors or inconsistencies. (Tab 18, 3-5-09 Duggan Dep. 145-47; Tab 20, 5-18-09 Duggan Dep. 159.)

239. Thus, because the DMERCs' treatment varied across DMERCs and for certain time periods within DMERCs, Duggan sometimes treated the NovaPlus label as a brand as the DMERCs did under the NovaPlus model. (Tab 18, 3-5-09 Duggan Dep. 146, 152-53.)

240. Because the regulations allowed payments to be based on "the lowest brand AWP" whenever it was lower than the median of generic AWPs, in Dr. Duggan's "but-for" world, the "revised NovaPlus AWP" now becomes the hypothetical "lowest brand AWP." (Tab 18, 3-5-09 Duggan Dep. 140-141, 159-60.)

241. As a result, the NovaPlus prices establish the payment basis for *all* quarters and *all* ipratropium bromide claims. (Tab 18, 3-5-09 Duggan Dep. 140-141, 159-60.)

242. Although the misclassification of NovaPlus as brand had no impact upon Medicare payments in the real world (because the NovaPlus and Roxane label AWPs were identical at all times), under Dr. Duggan's "but for" world, it has a massive impact. (Tab 20, 5-18-09 Duggan Dep. 158.) During any quarter in which Dr. Duggan finds liability in the NovaPlus model, he assigns *all* J-Code payments to Roxane, which include claims for payments for not only Roxane products, but any claims submitted for other manufacturers' ipratropium products. (Tab 20, 5-18-09 Duggan Dep. 157-58.)

243. There is a significant difference in Duggan's calculation of alleged damages under No-NovaPlus model (*i.e.*, excluding NovaPlus label products) and NovaPlus models (*i.e.*, incorporating both the Roxane label and NovaPlus label); specifically, Dr. Duggan calculates an alleged damage figure of $234 million for his No-NovaPlus Model but $1.17 billion under the model that includes the NovaPlus label product. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 3; Tab 18, 3-5-09 Duggan Dep. 183.)

244. Dr. Duggan later conceded that the No-NovaPlus scenario recognizes that NovaPlus had "virtually no utilization" despite its "massive effect" on his damages calculations. (Tab 20, 5-18-09 Duggan Dep. 155-56.) He testified that he understands that there are good arguments that NovaPlus is not a brand drug and remains "agnostic" as to whether the NovaPlus or No-NovaPlus damages model is more appropriate. (Tab 18, 3-5-09 Duggan Dep. 181-82; Tab 20, 5-18-09 Duggan Dep. 155-56, 169.) He testified that one could make a good case for the No-NovaPlus scenario based on the fact that the DMERCs may have misclassified NovaPlus as a brand, the very low utilization of the NovaPlus products under Medicare Part B and Roxane's

declining marketshare during the time period when Dr. Duggan calculates damages purportedly attributable to the NovaPlus prices. (Tab 20, 5-18-09 Duggan Dep. 157-60.)

H. The Government's Damages Are Also Inflated By Their Expert's Failure To Discount Damages As A Result of Three DMERCs Failure To Include NDCs For A Generic Product In Their Arrays.

245. Two ipratropium bromide inhalation solution products manufactured by Zenith Goldline appeared in the April 2000 monthly Red Book paper update and in the April 2000 electronic Red Book for Windows publication. (Tab 178, April 2000 RedBook Update at 43; Tab 189, AWP039-2444 (April 2000 Red Book CD Printout).).

246. One of these Zenith Goldline ipratropium bromide products (NDC 00172-6407-44) had an AWP of $44.10. CD Printout; Tab 189, AWP039-2444 (April 2000 RedBook CD Printout).) The second Zenith Goldline ipratropium bromide product (NDC 00172-6407-49) had an AWP of $105.60 price listed in CD printout. (Tab 178, April 2000 RedBook at 43; Tab 189, AWP039-44 (April 2000 Red Book CD Printout).)

247. AdminaStar Federal included these two Zenith Goldline NDCs on a non-final array for the second quarter of 2000. (Tab 185, Roxane Ex. 118 at AWP033-45 (AdminaStar Federal arrays).) It is unclear whether AdminaStar Federal decided to use that array to calculate the maximum allowable cost for that quarter. (Tab 23, 8-27-08 Eiler Dep. 297-301.)

248. From the third quarter of 2000 through the second quarter of 2002, AdminaStar added the Zenith Goldline drugs to the generic portion of the pricing arrays it used for ipratropium bromide. (*See* Tab 185, Roxane Ex. 118 at AWP033-72–AWP033-73, AWP033-0268-69, AWP033-1128–29, AWP033-0987–88, AWP033-0862, AWP033-1742, AWP033-0737–738, AWP033-055051, AWP033-1474 (AdminaStar Federal arrays).)

249. The Government's damages expert, Dr. Duggan, found that once these values were added to AdminaStar's arrays, the AWPs for Roxane's drugs no longer affected the calculation of the median AWP for the J7644 J-Code. (Tab 188, D. Williams Aff. ¶ 13.)

250. After the second quarter of 2000, Dr. Duggan's methodology properly dictates that there should be no damages for Roxane from that time onward. (*Id*.)

251. Unlike AdminaStar Federal, the other three DMERCs did not include the Zenith Goldline ipratropium bromide products in any of their pricing arrays. (*See* Tab 186, Roxane Ex. 46 (Palmetto arrays); Tab 187, Helton Ex. 58 (Cigna arrays); Tab 152, Ex. A to Decl. of C. King (DMERC-A arrays).)

252. As a result, the Government's damages expert, Dr. Duggan calculated damages for DMERC-A, Palmetto, and Cigna after the second quarter of 2000. (Tab 188, D. Williams Aff. ¶ 14.) Dr. Duggan calculates damages for these quarters totaling $87.99 million. (*Id*.)

XVIII. DIVESTMENT OF ORAMORPH SR, ROXANOL & ROXICODONE

253. On September 28, 2001, Roxane divested certain drugs to Elan Pharma International Ltd. ("Elan"), including all Oramorph SR (0054-4793-25, 0054-4805-27, 0054-4790-25, 0054-4805-25, 0054-4805-19, 0054-4792-25), Roxanol (0054-3751-58, 0054-3751-50, 0054-3751-44), and Roxicodone (0054-4658-25, 0054-4665-25) NDCs at issue in this Action. (Tab 190, Asset Purchase Agreement ¶ 1.1 at 8-9; U.S. Compl. Ex A (noting that Roxane divested each of these NDCs to Elan)

254. After the divestment, Elan owned all of the NDAs associated with these NDCs and assumed all liabilities and obligations arising from the manufacture, sale, and marketing of these products. (Tab 190, Asset Purchase Agreement ¶ 1.1 at 2, ¶ 2.1(d) at 11)

XIX. THE GOVERNMENT HAS NO EVIDENCE SUPPORTING ITS UNJUST ENRICHMENT OR AZATHIOPRINE MEDICARE CLAIMS.

255. In response to a Roxane interrogatory served October 1, 2008 asking for evidence supporting the unjust enrichment claim, the Government stated the following:

> Through reporting inflated prices, Roxane ensured that its customers received inflated reimbursement from Medicare and Medicaid. Roxane then knowingly promoted "spreads" between its fraudulently inflated prices and its actual sales prices as an inducement to its customers.

(Tab 191, U.S. Objs. & Resps. to Roxane's 1st Set of Interrogs. at 55)

256. Roxane's ipratropium bromide sales decreased during the time period when the Government's purported "spreads" were growing dramatically. (Tab 69, D. Williams Dep. 577-78; Tab 192, 3-13-09 Expert Report of Darrell L. Williams at 12)

257. In addition, the Government's damages expert failed to conduct any Medicare-specific analyses or render Medicare-specific opinions with respect to azathioprine. (Tab 18, 3-5-09 Duggan Dep. 74)

XX. THE GOVERNMENT'S METHODOLOGY OF ALLEGED MEDICAID DAMAGES.

A. Overview Of The Government's Methodology For Calculating Alleged Medicaid Damages.

258. The Government's expert, Dr. Mark G. Duggan, utilizes data from a variety of sources to determine the amounts by which federal-State Medicaid program spending purportedly would have changed if the alternative prices that he calculates, *i.e.*, "revised" Average Wholesale Prices ("Revised AWPs") and Wholesaler Acquisition Costs ("Revised WACs"), had been used as a basis of payment. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 9)

259. Dr. Duggan focuses on the 35 NDCs listed in the United States' First Amended Complaint ("Medicaid Subject Drugs"), which relate to nine different drug products:

Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, ipratropium bromide, Oramorph SR, Roxanol, Roxicodone, and Sodium Polystyrene Sulfonate. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 9; Tab 137, FAC Ex. A.)

B. Description Of Datasets Utilized By The Government.

260. When calculating Medicaid damages, Dr. Duggan utilizes five different datasets relating to the Medicaid Subject Drugs. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 25-30, Tables 29 and 31A-B)

261. The first dataset utilized by Dr. Duggan comprises State Medicaid claims data that was produced by the following sixteen State Medicaid programs to the United States (hereinafter, the "State Medicaid Claims Data"): California, Florida, Georgia, Illinois, Kentucky, Louisiana, Massachusetts, Michigan, Missouri, New Jersey, New York, North Carolina, Pennsylvania, Texas, Virginia and Wisconsin. Collectively, these sixteen States are referred to as the "Sixteen State Sample." (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report, Table 29)

262. Dr. Duggan has access to Medicaid claims data for an additional fifteen States that was produced to the United States ("Additional State Medicaid Claims Data"): Alaska, Arkansas, Connecticut, Delaware, Hawaii, Idaho, Iowa, Kansas, Minnesota, Nebraska, New Mexico, Rhode Island, South Carolina, Utah and Wyoming. Dr. Duggan did not use, however, the Additional State Medicaid Claims Data in connection with his calculation of alleged Medicaid damages. (Tab 188, D. Williams Aff. ¶ 2.) The Government failed to obtain and produce State Medicaid Claims Data from the other eighteen State Medicaid programs at issue in this lawsuit.

263. State Medicaid Claims Data and Additional State Medicaid Claims Data vary slightly by States but they typically include the following information for each claim paid by a State Medicaid program: date of service; actual paid amount; NDC; actual billed amount;

professional or dispensing fee; copayment amount; third party payment; ingredient cost; provider ID; a field indicating if a State maximum allowable cost ("MAC") or federal upper limit ("FUL") was used to determine the reimbursement amount for the claim, as well as the unit price for that MAC or FUL for each claim; and, data concerning the basis of payment for a particular claim (*e.g.*, whether a claim was paid on an AWP or WAC). (Tab 188, D. Williams Aff. ¶ 3.)

264. The second dataset utilized by Dr. Duggan consists of State Medicaid Research Files ("SMRF" data) that was produced by CMS for the time period 1991 through 1998. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 28-30, Tables 29 and 31A-B)

265. The third dataset utilized by Dr. Duggan consists of Medicaid Analytic eXtract General Information ("MAX" data) that was produced by CMS for the time period 1999 through 2004 (collectively, "SMRF-MAX" datasets). (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 28-30, Tables 29 and 31A-B)

266. The fourth dataset utilized by Dr. Duggan consists of Medicaid Statistical Information Statistics ("MSIS" data) that was produced by CMS for the time period 1999 through 2005. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 28, n.13)

267. Although the SMRF-MAX and MSIS datasets vary, they each typically include the following information for each claim paid by a State Medicaid program: date of service; paid amount rounded to the nearest dollar; NDC; quantity; billed amount rounded to the nearest dollar; third party payment; and, provider ID. (Tab 188, D. Williams Aff. ¶ 5.) The SMRF-MAX and MSIS datasets, unlike the State Medicaid Claims Data and Additional State Medicaid Claims Data, do ***not*** provide the following information for each claim: the specific amount actually paid on the claim; the specific amount actually billed by the provider; dispensing fee; copayment amount; and, a field indicating whether a claim was paid on a MAC

or FUL. (*Id.*) Thus, these datasets do not contain the data required to calculate the basis of payment for a claim. (*Id.*)

268. The fifth dataset utilized by Dr. Duggan consists of State Drug Utilization Data ("SDUD") that was produced by CMS for the time period 1991 through 2008. (Tab 166, Duggan Report at 25-28, Tables 29 and 31A-B) SDUD provides only aggregated, or summary, claim information on a State-specific, NDC-quarter level. (*Id.*) SDUD typically includes the following information for each State: NDC-quarter; quantity; total number of units reimbursed by the State Medicaid program; total number of prescriptions for the NDC; and the total dollar amount paid by the State Medicaid Program for that NDC during the given quarter. (Tab 188, D. Williams Aff. ¶ 6.) SDUD does ***not*** include the following information: the specific amount actually paid on the claim; the specific amount actually billed by the provider; dispensing fee; copayment amount; a field indicating whether claims were paid on a MAC or FUL. (*Id.*) Therefore, SDUD does not contain the data required to calculate the basis of payment for a claim. (*Id.*) Collectively, the SDUD, SMRF-MAX and MSIS datasets are referred to as the "CMS Datasets."

C. Dr. Duggan Did Not Determine Whether State Medicaid Programs Complied With Their CMS-Approved Regulatory Formulae When Paying Medicaid Claims.

269. Dr. Duggan did not determine whether CMS approved the Medicaid reimbursement formulas utilized by the State Medicaid Programs in the payment of claims. Duggan testified that "I did not examine whether the adjudication methods were approved by CMS." (*Id.*)

270. State Medicaid programs do not always adhere to their CMS-approved regulatory formulae when paying Medicaid claims. For example, in Florida, an erroneous computer programming change caused the State Medicaid program to unintentionally remove its

WAC-based EAC formula from its reimbursement logic. (Tab 67, 5-25-05 Wells Dep. 453-59) In addition, the Hawaii reimbursement system was incorrectly set up "so that the FUL price would override the Hawaii MAC price . . . even if the FUL price was higher." (Tab 16, 4-29-08 Donovan Dep. 186-87; Tab 193, HHD041-076-077 (Hawaii State Plan); Tab 194, HHD041-072-075; Tab 195, HHC016-342-343; Tab 196, HHD041-0061; Tab 197, HHD041-065) Also, prior to 2003 in Alaska, drugs subject to a FUL were reimbursed only at the lower of the FUL or the billed charge, not the AWP-based EAC, because Alaska's reimbursement methodology "failed to incorporate" the EAC. (Tab 4, 8-21-08 Campana Dep. 240-42; Tab 198, Abbott Ex. 1122)

271. Massachusetts paid claims in amounts that exceeded the EAC and the FUL. *Massachusetts v. Mylan Labs.*, No. 03-11865, 2008 WL 5650859, at *4 (D. Mass. Dec. 23, 2008) ("[i]n certain cases, [Massachusetts] reimbursement exceeded the EAC and the FUL.").

272. The Office of Inspector General found in its review of reimbursement data from all State Medicaid programs for FY 2001 that some States paid for certain drugs in amounts above the "Federal upper payment limits." (Tab 199, OEI-05-02-00681, Variation In State Medicaid Drug Prices, September 2004, p. iv-v)

273. From 1999-2003 Dr. Duggan calculates alleged damages for claims reimbursed by the Massachusetts Medicaid program based on an AWP-based formula. (Tab 188, D. Williams Aff. ¶ 16.)

274. Similarly, Alabama Medicaid paid for claims using an AWP-based EAC, despite the fact that this payment basis was not authorized in the CMS-approved State Medicaid Plan. (Tab 200, HHD086-010; Tab 201, HHD086-0011-012; Tab 202, ALMED-808004-808005.)

D. Dr. Duggan Did Not Determine The Basis Of Payment For Medicaid Claims.

275. Except for New York claims, Dr. Duggan did not determine the payment basis of any of the Medicaid claims at issue. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91) Dr. Duggan also testified that he did not determine whether Roxane AWPs or WACs were in fact used by a particular State Medicaid program. (*Id.* at 300-301)

276. Many of the payment bases utilized by State Medicaid programs do not utilize the AWPs and WACs published in the drug pricing compendia. For example, in order to receive reimbursement, providers must submit on each Medicaid claim a price referred to as the usual and customary charge ("U&C"). *See* 42 C.F.R. 447.331(b)(2) (payment bases include "[p]roviders' usual and customary charges to the general public"). Each State has its own definition for U&C, and those definitions can materially vary from State-to-State. Some States define U&C as the price paid by retail or cash-paying customers. (*See, e.g.*, Tab 43, 11-18-08 J. Parker Dep. at 189-91 (U&C defined as the "price that a pharmacy would pay to a cash-paying customer"); Tab 54, 11-04-08 Tomlinson, II Dep. 373-74. However, other States have adopted "best price" or "most favored nation" definitions, which require the pharmacy to submit the lowest price charged or accepted from any customer or reimburser. (*See, e.g.*, Tab 29, 11-24-08 Hautea-Wimpee Dep. 308-10, 319-21; Tab 211, J. Dubberly Dep. Ex. 7, at VI-1; Tab 70, 12-3-08 J. Young Dep. at 202; *Massachusetts v. Mylan Labs, et al.*, 2008 WL 5650859, at *3 (D. Mass. Dec. 28, 2008); Tab 203, Roxane VA Ex. 10, at 72, 75, 77, 85) No State Medicaid program defines U&C on the basis of Roxane's AWPs or WACs. Dr. Duggan did not determine which of the Medicaid claims at issue were paid on the basis of U&C in all States. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91).

277. Rhode Island only pays Medicaid claims on the basis of the FUL or the U&C, if no WAC price was available in the drug pricing compendia. (Tab 70, 12-3-08 J. Young Dep. at

136-37) From 1998 onwards, Roxane did not supply WAC prices to the drug pricing compendia for its generic drugs, including azathioprine, diclofenac sodium, furosemide, hydromorphone, ipratropium bromide, and sodium polystyrene sulfonate. (Tab 65, 5-11-07 Waterer Dep. 666-69) Removing claims for these NDCs after 1998Q1 reduces alleged damages from $258,983 to $53,147. (Tab 188, D. Williams Aff. ¶ 18.)

278. Generic drugs often are subject to FULs, as well as the State maximum allowable cost ("State MAC") prices developed by State Medicaid programs. (*See, e.g.*, Tab 139, Ex. 139, DOJ Supp. Response to Interrogatory No. 7 at 9; Tab 204, *Generic Drug Cost Containment in Medicaid: Lessons from Five State Maximum Allowable Cost (MAC) Programs*, at 4 ("According to the National Pharmaceutical Council, 30 States had MAC lists in 2001; since then, a number of States have created new MAC lists")); Tab 205, *Medicaid Prescription Reimbursement Information by State – Quarter Ending March 2009* (45 State Medicaid programs have established MAC programs)) Except for New York, Dr. Duggan did not determine whether FUL prices applied to the Medicaid claims at issue. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91)

279. Many State Medicaid programs do not base their MAC prices on published prices. (*See, e.g., California, ex rel. Ven-A-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc.*, 478 F.Supp.2d 164, 180 (D. Mass 2007) (finding California MAIC program was not based on published benchmarks such as AWP or WAC); (Tab 68, 3-14-08 Wiberg Dep. 64-66) (Minnesota's MACs are based on actual acquisition costs provided by a group of pharmacies); (Tab 17, 12-15-08 Dubberly Dep. 67-68, 207; 306-307) (MACs determined by pharmacy benefit managers); (Tab 29, 11-24-08 Hautea-Wimpee Dep. 105-10) (Tab 206, AWP-IL-00025984) ("Generally, pharmacists in attendance seemed to understand the methodology used to establish

State MAC rates [in Illinois], which is based upon actual acquisition costs obtained from providers.") (Tab 207, AWP-IL-00001108) (Tab 2, 12-10-08 Bridges Dep. 65, 244-251) (Tab 3, 12-11-08 Bridges Dep. 474-480) (Tab 47, 3-28-08 Sharp Dep. 62-66, 140, 250-51) (Tab 61, 3-26-08, J. Walsh Dep. 98) (Tab 25, 12-9-08 Fine Dep. 151-52, 201-204) (Tab 35, 3-25-08 Kenyon Dep. 37-40) (Tab 6, 12-2-08 Cheloha Dep. 128-132; 164-65) (Tab 13, 10-30-07 Collins Dep. 72-77) (Tab 208, DHCF Current Policy, Brand Medically Necessary and Medicaid Maximum Allowable Cost at 2) (Tab 209, Texas Health and Human Services Commission, Vendor Drug Program, Pharmacy Provider Handbook, March 1, 2006) (Tab 210, OIG Oct. 2003, "State Strategies to Contain Medicaid Drug Costs," at 13 (OEI-05-02-00680). Dr. Duggan did not determine whether MAC prices applied to any of the Medicaid claims at issue. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91)

E. The Calculation Of Alleged Damages Based On Actual State Medicaid Claims Data Within The Sixteen State Sample.

280. Dr. Duggan calculates alleged Medicaid damages for his Sixteen State Sample where State Medicaid Claims Data is available to him. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-93, Table 29) Dr. Duggan does not attempt to calculate damages on a claim-by-claim, State-by-State, basis. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96)

281. Dr. Duggan's calculation purportedly reflects the difference between the amounts actually paid by State Medicaid programs for the Medicaid Subject Drugs and the amounts that Dr. Duggan purports should have been paid, if the State Medicaid programs used his "Revised AWPs" or "Revised WACs" as a basis of payment. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-93)

282. Before Dr. Duggan calculates any alleged Medicaid damages, he limits the State Medicaid Claims Data to include only claims relating to the Medicaid Subject Drugs and the relevant periods. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 11, Tables 13A-29) Thus, Dr. Duggan does not include any Medicaid claims before February 15, 1999 for non-ipratropium bromide drugs, and pre-1996 for ipratropium bromide. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 11) Dr. Duggan also does not include any claims after October 1, 2001 for drugs that Roxane divested to Elan Pharma International Limited on September 28, 2001 (Roxanol (0054-3751-44, 0054-3751-50, 0054-3751-58), Roxicodone (0054-4658-25, 0054-4665-25), Oramorph (0054-4805-19, 0054-4805-25, 0054-4805-27, 0054-4790-25, 0054-4792-25, 0054-4793-25)). (Tab 166, Duggan Rebuttal Report 19-20; *see also* Tab 166, First Am. Compl., Ex. A)

283. Dr. Duggan also eliminates a number of invalid claims that appear in the State Medicaid Claims Data. For example, Dr. Duggan typically eliminates the following categories of claims, among others: (1) where the paid amount, billed amount, or quantity is less than or equal to 0; (2) where an amount paid by the State Medicaid program is greater than the amount billed by the healthcare provider (U&C); and (3) and where the dispensing fee in the claims data does not match the dispensing fees reflected in the Government's expert's surveys of purported State Medicaid reimbursement formulae. (Tab 188, D. Williams Aff. ¶ 4.).

284. When analyzing the State Medicaid Claims Data, Dr. Duggan eliminates over 800,000 claims from his calculations of alleged Medicaid damages. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-92). For example, Dr. Duggan discards hundreds of thousands of claims because the paid amount exceeded the amount actually billed by the provider. With respect to Georgia, for instance, Dr. Duggan eliminates over 214,000 claims (56% of the total

claims he analyzed in that State) because the amount paid on these claims exceeded the amount billed by the provider. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 65) Under Georgia's governing Medicaid regulations which utilized a "lower of" reimbursement methodology, the Medicaid payment on a drug claim should never have been greater than the provider's billed charge. (*See, e.g.*, Tabs 211-216, J. Dubberly 12-15-08 Dep. Exs. 7-12; Tab 217, HHC008-0012) Dr. Duggan also eliminates thousands of claims from his Medicaid difference calculations when the dispensing fee was inconsistent with the State Medicaid reimbursement policy. (*See, e.g.*, Tab 166, Duggan Ex. 001. 02-06-09 Duggan Report 80) For example, when analyzing the State Medicaid Claims Data for Michigan, Dr. Duggan drops 22,314 claims "with an unsupported dispensing fee." (*Id.*)

285. After dropping the various invalid claims described above, for the remaining claims Dr. Duggan calculates what the State Medicaid program purportedly would have paid on a particular claim if his "Revised AWPs" or "Revised WACs" had been utilized. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 9-11)

286. To determine what a State Medicaid program purportedly would have paid on a Medicaid claim, Dr. Duggan first adds a twenty-five percent markup to his "Revised WAC," if the State utilizes "AWP" in its definition of Estimated Acquisition Cost ("EAC"). (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 10) If the State utilizes WAC, however, Dr. Duggan does not add a twenty-five percent markup to his "Revised WAC." (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 41-42) Next, Dr. Duggan inputs the "Revised AWP" (or "Revised WAC") into the State's EAC formula. (*See e.g.*, Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 31-32) Dr. Duggan inserts his "Revised AWP" (or WAC) into the State reimbursement

formula to arrive at an adjusted payment amount, which he uses as the basis for his alleged damages calculation. (*Id*.)

F. Intrastate Extrapolations To CMS Datasets Within The Sixteen State Sample To Estimate Alleged Damages.

287. Within the Sixteen State Sample, there are a number of quarters where State Medicaid Claims Data is lacking or incomplete. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report Table 29) In fact, Dr. Duggan does not possess complete State Medicaid Claims Data for any of the States within the Sixteen State Sample. (*Id.*)

288. Because Dr. Duggan does not possess complete State Medicaid Claims Data for any State within his Sixteen State Sample, he cannot calculate "damages" on a claim-by-claim basis for every quarter for each of the Medicaid Subject Drugs. Instead, Dr. Duggan performs an intrastate extrapolation (utilizing one of the other CMS Datasets) to estimate alleged damages for those quarters where State Medicaid Claims Data is lacking. (*See e.g.*, Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-93, Table 29)

289. In particular, Dr. Duggan lacks State Medicaid Claims Data for the following quarters: California (2007Q4 through 2008Q1); Florida (2006Q1-2008Q1); New York (2007Q3-2008Q1); Pennsylvania (1996Q3-1998Q2 and 2007Q2-2008Q1); Missouri (1996Q3-1997Q4); Illinois (2007Q1-2008Q1); Massachusetts (2008Q1); Texas (2006Q1-2008Q1); Georgia (1996Q3-2000Q3 and 2007Q1-2007Q4); North Carolina (1999Q1-2000Q4) and (1996Q3-1998Q4), (2007Q2-2008Q4); New Jersey (2007Q1-2008Q1); Michigan (1996Q3-2000Q3 and 2007Q3-2008Q1); Louisiana (2002Q1-2002Q2 and 2007Q4-2008Q1); Kentucky (2005Q2-2008Q1); Wisconsin (2006Q1-2008Q1) and Virginia (2007Q1-2008Q1). (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report Table 29) Dr. Duggan applies an intrastate extrapolation for each NDC and in each quarter during the relevant period

for which he lacks State Medicaid Claims Data. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report Table 29)

290. Dr. Duggan applies an intrastate extrapolation to one of the four different CMS Datasets. (*Id.*) This intrastate extrapolation is based only on State Medicaid Claims Data from the actual State in which such data is missing. For example, Dr. Duggan does not perform an intrastate extrapolation to a quarter where he lacks State Medicaid Claims Data in Virginia using data related to the payment of Kentucky Medicaid claims.

G. Interstate Extrapolations To CMS Datasets For The Remaining Thirty-Three State Medicaid Programs To Estimate Alleged Damages.

291. Dr. Duggan uses an interstate extrapolation to estimate "damages" for the remaining thirty-three State Medicaid programs in which he does not utilize State Medicaid Claims Data. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96) In particular, Dr. Duggan applies an interstate extrapolation for each NDC and in each quarter during the relevant period for the thirty-three State Medicaid programs that are not included in the Sixteen State Sample. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96, Tables 31A-B) Thus, none of the damages Dr. Duggan estimates for these thirty-three State Medicaid programs is based on a claim-by-claim determination. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96; *see also* Tab 218, *Questions by Chairman Tom Coburn for Daniel R. Levinson, Inspector General,* U.S. Department of Health and Human Services (April 28, 2006), available at http://coburn.senate.gov/oversight/index.cfm`FuseAction=Hearings.Home&ContentRecord_id=47a389df-7e9c-9af9-765c-d9f650ad0d43&Issue_id=

292. Similar to intrastate extrapolation, Dr. Duggan applies an interstate extrapolation to one of the four different CMS Datasets. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-69) As part of his interstate extrapolation, Dr. Duggan identifies for each NDC and quarter,

the number of States within the Sixteen State Sample in which he possesses State Medicaid Claims. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 94). In some NDC-quarters Dr. Duggan has State Medicaid Claims Data for far fewer than all of the States comprising the Sixteen State Sample. (Tab 188, D. Williams Aff. ¶ 17.) For example in 2007Q4 for NDC 0054-4297-31, only two States within the Sixteen State Sample have State Medicaid Claims Data. (*Id.*) For this NDC and in this quarter, Dr. Duggan utilizes State Medicaid Claims Data from just two States to extrapolate to thirty-three other State Medicaid programs. (*Id.*)

293. Unlike intrastate extrapolation, however, Dr. Duggan's interstate extrapolation is based on State Medicaid Claims Data from different State Medicaid programs. In other words, by way of example, for NDC 0054-4297-31 in the third quarter of 2007, Dr. Duggan performs an interstate extrapolation to estimate damages in Rhode Island by relying on data related to the payment of claims in the California, Louisiana, Massachusetts and Missouri State Medicaid programs.

H. The Total Amount Of Alleged Medicaid Damages Based On Interstate And Intrastate Extrapolations To CMS Datasets.

294. Dr. Duggan calculates over $3.5 million in alleged Medicaid damages based on the intrastate extrapolations he performs within his Sixteen State Sample. (Tab 219, Duggan Ex 007, Duggan Rebuttal Report, Table 29 Revised)

295. Dr. Duggan calculates an additional $20.3 million in alleged Medicaid damages based on the interstate extrapolation he performs for the other 33 State Medicaid programs that are not included in the Sixteen State Sample. (*Id.*)

296. Overall, Dr. Duggan calculates over $23.8 million in alleged Medicaid damages based upon intrastate and interstate extrapolations to CMS Datasets. (*Id.*)

I. Total Alleged Medicaid and Medicare Damages Post-December 31, 2000.

297. Dr. Duggan calculates alleged damages for Medicaid and Medicare claims submitted for payment post-December 31, 2000. (Tab 188, D. Williams Aff. ¶ 8.). When claims paid after December 31, 2000 are excluded from the alleged damages calculation, Dr. Duggan's Medicaid damages are reduced by $43.3 million and his Medicare damages are reduced by almost $47 million in his Roxane only scenario (Novaplus excluded) and by over $732 million in his Roxane and Dey scenario (Novaplus excluded) (*Id*.)

Dated: June 29, 2009

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 29, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale
John W. Reale